HEALTH AND CARE BILL

Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee

CONTENTS

I. INTRODUCTION

1. This memorandum has been prepared for the Delegated Powers and Regulatory Reform Committee to assist with its scrutiny of the Health and Care Bill ("the Bill").This memorandum identifies the provisions of the Bill that confer powers to make delegated legislation, directions, guidance or schemes and explains in each case why the power has been taken and the nature of, and reasons for, the procedure selected. This memorandum reflects the Bill as introduced to the House of Commons on 6th July 2021.

II. CONTEXT AND PURPOSE

2. The Bill is intended to give effect to the policies requiring primary legislation that were set out in the White Paper *Integration and Innovation: working together to improve health and social care for all*, published in February 2021. The Department's proposals in the Bill build on the NHS's own in the Long Term Plan published in 2019. The Bill contains provisions aimed at promoting working together in the health service to integrate care, reducing bureaucracy, improving accountability and enhancing public confidence, as well as measures on a variety of other specific topics.

3. The Bill therefore contains provisions on a wide range of policies. It contains 135 clauses over six Parts, and has sixteen Schedules:

Part 1 – Health Service in England

4. Part 1 of the Bill provides for improved integration, collaboration and reform of the Health Service in England. It reforms the role of the NHS Commissioning Board (renamed "NHS England"), establishes Integrated Care Boards ("ICBs") and merges a number of NHS Bodies. It confers functions on the Secretary of State to direct NHS England, as well as other NHS bodies in specific circumstances, and reforms the functions of NHS trusts and NHS foundation trusts (while keeping the legal distinction between those two types of providers). It also reforms the NHS payment scheme, and procurement and competition rules as they apply in relation to the NHS.

5. The ICB proposal is to establish a new NHS body following the abolition of Clinical Commissioning Groups, bringing together NHS organisations and partners from local government and beyond. The clauses specify the requirements for establishment of ICBs, their functions, duties and governance. The Bill will establish the framework for financial operations for ICBs which includes joint duties with partner NHS trusts and NHS foundation trusts as to expenditure and resource use limits. The clauses place a duty on each ICB and local authority who falls within that area to establish a joint committee known as an Integrated Care Partnership, and confer the function of preparing a system level strategy on that Integrated Care Partnership.

Part 2 – Health and Adult Social Care: Information

6. Part 2 of the Bill contains provisions relating to information standards, the Health and Social Care Information Centre, Medicine Information Systems, provisions relating to sharing and collection of information for health and social care purposes and provisions relating to enforcement.

Part 3 – Powers of the Secretary of State to transfer or delegate functions

7. Part 3 of the Bill outlines provisions relating to the Secretary of State's powers to transfer or delegate functions. The provisions relate to the transfer of functions between bodies and the power to provide for the exercise of functions of the Secretary of State. Provisions in this part of the Bill stipulate the relevant bodies and the scope of those powers.

Part 4 – Health Services Safety Investigations Body

8. Part 4 of the Bill establishes the Health Services Safety Investigations Body (the 'HSSIB') as an independent statutory body, with powers to conduct investigations into incidents that occur in England during the provision of health care services which have, or may have, implications for the safety of patients.

Part 5 – Miscellaneous

9. Part 5 of the Bill outlines provisions relating to international healthcare, regulation and financial assistance in relation to social care, fluoridation of water supplies, advertising prohibitions in respect of less healthy food, hospital food standards, professional regulations and provisions pertaining to medical examiners.

Part 6 – General

10. Part 6 of the Bill provides for power to make consequential provisions, addresses regulations and financial provision and outlines the extent and commencement provisions.

General approach to delegated powers:

11. In deciding whether matters should be specified on the face of the Bill or dealt with in delegated legislation, the Department has carefully considered the need:
    a. to avoid too much technical and administrative detail on the face of the Bill;
    b. to provide flexibility for responding to changing circumstances, so that requirements can be adjusted without the need for further primary legislation; and
    c. to allow detailed administrative arrangements to be set up and kept up to date within basic structures and principles that are set out in primary legislation, subject to Parliament's right to challenge inappropriate use of powers.

12. There is strong support across the health and social care system for a more flexible legislative framework. Flexibility is essential both to give local health and care leaders greater flexibility to develop local solutions and to future-proof the legislation to enable the system to respond to the changing needs of the population and innovations in the way the health and care is delivered.

13. In deciding what procedure is appropriate for the exercise of the powers in the Bill, the Department has carefully considered in particular:
    a. whether the provisions amend primary legislation; and
    b. the importance of the matter to be addressed.

14. The Bill contains a total of 138 powers, 7 of which include power to amend primary legislation through secondary legislation. The latter are all subject to the affirmative procedure. These "Henry VIII" powers are proposed in order to ensure that legislation continues to operate effectively and the statute book is kept up to date regularly. The Henry VIII powers in the Bill are contained in the following provisions:

    a. Clause 11
    b. Clause 85
    c. Clause 87
    d. Clause 88
    e. Clause 123
    f. Schedule 16
    g. Clause 130

15. A significant number of the powers this Bill proposes to delegate are to persons or bodies other than the Secretary of State. This is in large part due to the Department of Health and Social Care working closely with a number of arm's-length bodies. These arm's-length bodies share in managing, or overseeing, the use of resources across the NHS, public health and social care. The largest of the agencies and public bodies supporting the Department is NHS England (and that will be merged with Monitor and NHS Trust Development Authority under the Bill as explained below). The Bill contains a number of powers delegated to NHS England in particular in relation to ICBs.

Abbreviations

16. This Memorandum contains the following abbreviations:

"the 1999 Act"	Health Act 1999
"the 2006 Act"	The National Health Service Act 2006
"the 2008 Act"	Health and Social Care Act 2008
"the 2012 Act"	Health and Social Care Act 2012
"ALB"	Arm's-length body

"CCG"	Clinical Commissioning Group
"CDEL"	Capital Departmental Expenditure Limit
"CQC"	Care Quality Commission
"DPRRC"	Delegated Powers and Regulatory Reform Committee
"EEA"	European Economic Area
"EU"	European Union
"EUWA"	European Union (Withdrawal) Act 2018
"FIC"	retained EU Regulation 1169/2011 on the provision of food information to customers
"FSA 1990"	Food Safety Act 1990
"HEEASAA"	Healthcare (European Economic Area and Switzerland Arrangements) Act 2019
"HSSIB"	Health Services Safety Investigation Body
"ICB"	Integrated Care Board
"MHRA"	Medicines and Healthcare Regulatory Authority
"the MMD Act"	Medicines and Medical Devices Act 2021
"NDPB"	Non-departmental public body
"Qualifying incident"	An incident within clause 80(1) (j200(1)). *The HSSIB has the function of investigating incidents that-* *(a) occur in England during the provision of health care services, and* *(a) have or may have implication for the safety of patients.*
"RoW"	Rest of World
"SpHA"	Special Health Authority
"TCA"	Trade and Cooperation Agreement
"TDA"	Trust Development Authority
"WIA"	Water Industry Act 1991

III. OVERVIEW OF DELEGATED POWERS

Part 1 - Health Service in England: Integration, Collaboration and Other Changes

17. The Bill proposes to formally merge NHS England and NHS Improvement (currently made up of Monitor and the NHS TDA). In connection with this the following powers are proposed:

    a. A power for the Secretary of State to direct NHS England as to the form and content of consolidated accounts which NHS England is under a duty to prepare
    b. A regulation making power for the Secretary of State to make clear that any reference to an employee of NHS England includes persons seconded to NHS England

18. A core proposal of the Bill is the creation of a new type of NHS body called ICBs and the abolition of CCGs. ICBs and integrated care partnerships will bring together NHS organisations and partners from local government and beyond.

19. The Bill proposes a series of direction making powers conferred on the Secretary of State and NHS England relating to the financial duties of NHS England, of ICBs and of ICBs working jointly with partner NHS trusts and NHS trusts. Many of these powers are the same as powers that already exist in the 2006 Act in relation to CCGs, and are being restated so as to relate to ICBs and preserve the existing financial controls that exist currently. The direction making powers in relation to financial controls are intended to impose limits on expenditure and resource use, as well as assist the NHS bodies to calculate expenditure and resource use against those limits by describing (for example) what should, and should not, be treated as expenditure and resource use for the purposes of those sections. There are also a number of regulation making powers conferred on the Secretary of State. Regulations under the ICB provisions will provide for the appointed day upon which CCGs will be abolished and NHS England's duty to establish ICBs will come into force, they will set out exceptions as to the rules NHS England will publish on ICB responsibility, they will also in places expand ICB responsibility for the purposes of certain duties to commission services, and regulations will also enable the Secretary of State to impose requirements in relation to matters that must be included in the constitution of an ICB. There are also powers to issue guidance conferred on the Secretary of State and NHS England to help ICBs discharge their functions effectively. The powers include general guidance on all of the functions of an ICB, and more specifically on matters such as complying with a requirement to make payments to providers, the preparation of the joint capital resource use plan and on the preparation of the integrated care strategy.

20. A new NHS payment scheme is proposed in the Bill, to replace the NHS tariff. The nature of setting rules for prices to be paid to NHS providers is such that a number of powers need to be delegated, as is currently the case with the NHS tariff. Powers are proposed for NHS England to publish the payments scheme, and to give NHS England a power of direction

over commissioners where they fail to comply with rules in the payment scheme. A power is also created for the Secretary of State to prescribe, through regulations, objection percentages for commissioners and for relevant providers of health care services, to the proposed NHS payment scheme.

21. The Bill makes provision in relation to capital expenditure by NHS England. It is proposed that the Secretary of State will give directions to NHS England in relation to each financial year, pursuant to section 223D of the 2006 Act to specify the total capital and revenue resource limit for that year. A power is also proposed for the Secretary of State to direct NHS England that a given amount of its annual allotment under 223B is to be used for purposes relating to service integration, and how this amount may be used. Further, the Bill seeks to create a power for NHS England to make orders imposing limits on capital expenditure of any NHS foundation trust.

22. A new duty is to be imposed on bodies that arrange NHS services (NHS England and ICBs) and NHS providers of care (Trusts and Foundation Trusts) to have regard to the effect of their decisions on the health and wellbeing of the people of England, on the quality of services provided by other NHS bodies and on the sustainable resource use of other NHS bodies (operationally known as the “Triple Aim”). NHS England will have power to publish guidance on this duty. Further the Secretary of State will have power to issue guidance on co-operation between different NHS bodies and between NHS bodies and local authorities. A modification of NHS England’s powers to set licence conditions (which are to be inherited from Monitor) to bring them into line with the Triple Aim duty.

23. The Bill proposes that new powers of direction should be delegated to the Secretary of State in relation to NHS England’s exercise of its functions and to direct certain bodies to perform public health functions. It will also extend the Secretary of State’s powers to intervene in NHS reconfigurations.

24. A power is proposed for NHS England to publish guidance on joint appointments (that is, appointments of a person to a position in both a commissioning body and an NHS provider, and/or a position in both an NHS body and a local authority or combined authority) to provide clarity for organisations about when these will be appropriate.

25. Provisions in the Bill will give certain NHS bodies the power to arrange for other NHS bodies to exercise their functions, either alone or jointly with them. It is proposed that the Secretary of State have a regulation making power to provide that these joint working powers not apply, or apply only to a prescribed extent or subject to conditions. It is also proposed that NHS England have power to issue guidance to bodies on these joint working powers.

26. The Bill also further promotes patient choice. It will be mandatory for the Secretary of State, via regulations to impose standing rules on NHS England and ICBs about the arrangements NHS England and ICBs must make for enabling persons receiving certain treatments to exercise choice. The Secretary of State will have power to make other provisions for the purpose of requiring NHS England and ICBs to promote patient choice. NHS England will

have power to investigate potential failures by ICBs to promote patient choice, to direct them to put in place measures promoting it if they are failing to do so, and to publish guidance on its intended use of this power. NHS England will also have power to issue guidance on how it intends to exercise these powers.

27. In respect of procurement, a power is proposed for the Secretary of State, by regulations, to impose requirements on relevant authorities in relation to the procurement of health care services for the purposes of the health service, and for NHS England to publish guidance on compliance with these regulations.

28. A power is also delegated to the Secretary of State to create exceptions to the general rule that references to functions of a person include functions delegated to that person 61.

Part 2 – Health and Adult Social Care: Information

29. Part 2 of the Bill relates to information concerning healthcare generally and adult social care in particular. It contains provisions relating to information standards, the Health and Social Care Information Centre, Medicine Information Systems, provisions relating to sharing and collection of information for health and social care purposes and provisions relating to enforcement.

30. The delegated functions within this Part relate to information standards and include powers to waiver a person's requirement to comply with an information standard, to make regulations to provide for requirements and procedures in relation to waivers and regarding the procedure to be followed in connection with the preparation and publication of information standards requiring their periodic review. Additionally, regulation making powers enable the Secretary of State to impose a financial penalty on persons who fail to comply with information standards or information requirements or who provide false or misleading information.

31. Part 2 includes a power for Secretary of State to make regulations to create exceptions to the power for public bodies exercising health or adult social care functions to require information from each other or from private providers.

32. Further, there is a power for the Secretary of State to delegate powers and functions to the Health and Social Care Information Centre or a SpHA and to give directions about the exercise of those functions.

Part 3 – Secretary of State's Powers to Transfer or Delegate Functions

33. Part 3 of the Bill confers power on the Secretary of State to transfer functions between any of a defined group of relevant NDPBs, and to delegate functions of the Secretary of State to these NDPBs. The power proposed here is a Henry VIII power. The Bill also makes provision

for a number of consequential powers and power to make schemes for the transfer of property, rights and liabilities, in connection with regulations made under this Part.

Part 4 – The Health Services Safety Investigations Body

34. Part 4 of the Bill establishes HSSIB as an independent statutory body, with powers to conduct investigations into incidents that occur in England during the provision of health care services which have, or may have, implications for the safety of patients.

35. Delegated powers are created for the Secretary of State to create, by regulations, exceptions to the general rule that HSSIB may not disclose protected material to any person, and to direct HSSIB as to the exercise of its functions, or to investigate particular qualifying incidents. A power to make schemes for transfers of property, rights and liabilities from bodies previously exercising some functions to be exercised by HSSIB, is also proposed. Further, these provisions give the Secretary of State the power to direct NHS England or any other public body to exercise any of the investigation functions which had been previously exercised by the TDA as a transitional measure while HSSIB is being set up.

Part 5 – Miscellaneous

36. Part 5 of the Bill covers a range of topics associated with healthcare. It contains provisions relating to international healthcare, regulation and financial assistance in relation to social care, fluoridation, hospital food standards, professional regulations and provisions pertaining to medical examiners.

37. The delegated powers within this part relate to implementing reciprocal healthcare arrangements with non EEA countries, to extend the application of existing duties and powers of the CQC and the Secretary of State in relation to adult social care and prescribing which local authority functions in Part 1 of the Care Act 2014 will be subject to review by the CQC under new s46A, and to what extent they will be reviewed.

38. Part 5 also extends the scope of existing powers to make changes to legislation regulating healthcare professions to facilitate more flexible and proportionate regulation of healthcare professionals.

39. Part 5 also contains powers to make regulations to amend EU retained law concerning food labelling and creates powers to enable the Secretary of State to disapply the provision under which water undertakers must be reimbursed for the costs of water fluoridation schemes and to enable the Secretary of State to require the costs of water fluoridation schemes to be shared beyond central Government.

Part 6 – General

40. Part 6 of the Bill provides for power to make consequential provisions, sets out the parliamentary procedure for making regulations under the Bill and delegates power in respect of commencement provisions.

IV. ANALYSIS OF DELEGATED POWERS BY CLAUSE

PART 1

NHS England

Clause 3: NHS England mandate, amending section s13A of the 2006 Act – power to publish and revise the NHS England mandate
Power conferred on: Secretary of State
Power exercised by: Publishing or revising a mandate containing requirements
Parliamentary procedure: No procedure prior to revising the mandate, but if the mandate is revised it must be laid before Parliament

Context and purpose

41. The Department is making amendments to the provisions on the Secretary of State's duty to publish and lay before Parliament a mandate for NHS England (section 13A of the 2006 Act). The mandate sets out the Government's objectives for the NHS over a given period.

42. The amendments enable the Secretary of State to revise the mandate, and when doing so to lay the revised mandate before Parliament.

43. The amendments also remove the current duty to publish and lay a mandate before Parliament annually before the start of the financial year, and instead simply require the Secretary of State to have a mandate in place at all times. This will enable the Secretary of State to set a mandate at such time they considers appropriate (taking into account wider strategic decisions) and also to revise or replace it when the Secretary of State considers it necessary to do so.

44. Furthermore, the Department has removed the duty to include in the mandate the annual limits on capital and revenue resource use, and the power to do so for subsequent years (pursuant to section 13A(3) and (4)). Whilst the objectives and requirements in the mandate will need to continue to align with Government decisions on funding, those annual limits will instead be set out in directions made under section 223D. To ensure that the existing transparency is maintained, section 223D has been amended so that it is a requirement in the legislation to publish the financial directions and lay them before Parliament annually.

45. Finally, section 13A(5) is amended so that where the Secretary of State decides to specify in the mandate any matters by reference to which he intends to assess the Board's performance against (known operationally as "deliverables"), the Secretary of State can set those deliverables for the life of the mandate rather than just for the first year.

Justification for taking the power

46. This is a modification of an existing power for the Secretary of State to publish and lay before Parliament a mandate for NHS England. The mandate is the primary mechanism through which the Secretary of State ensures accountability from NHS England. Given that the objectives for NHS England are likely to change on a regular basis, this delegated power is required.

Justification for the procedure

47. As per the current provisions on the mandate, no Parliamentary procedure is proposed. However, the Secretary of State would have to lay the mandate before Parliament, and would remain accountable to Parliament in relation to NHS England.

Clause 4 : NHS England: wider effect of decisions , inserting new section 13NB into the 2006 Act – power to issue guidance in respect of the duty to have regard to the wider effect of decisions
Power conferred on: NHS England
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

48. The Department's intention is for organisations that plan NHS services (NHS England and ICBs) and statutory NHS providers of care (NHS trusts and NHS Foundation Trusts) to work better together for (a) better health and wellbeing for everyone, (b) better care for all patients, and (c) sustainable use of NHS resources – what is known operationally as the "Triple Aim". These Bill provisions will oblige bodies to consider the effect of their decisions on the three factors above when making decisions about the carrying out of their functions. The duty is to "have regard to [all] likely effects" of the relevant bodies' decision. It will apply to NHS England , NHS Trusts), NHS foundation trusts, and ICBs.

49. NHS England will have the power, under the new section 13NB , to publish guidance to itself and to other bodies about the discharge of the Triple Aim duty.

Justification for taking the power

50. The bodies that will be under the new Triple Aim duty will find it valuable to have detailed guidance about the discharge of the duty. The guidance is intended to cover detail as to the practical steps that may be necessary in order for a body to be compliant with its duty in various circumstances, and recommended means of evidencing compliance. This is a level of detail which cannot reasonably be provided in primary legislation. The body which will be best placed to provide this guidance is NHS England, as it has the greatest operational knowledge of the types of decisions faced by relevant bodies in the exercise of their functions.

51. The guidance is limited to being about the *discharge* of the duty – the guidance may not itself define or redefine the duty, but rather provide detail as to how the duty should be complied with. The power is therefore a relatively narrow one.

Justification for the procedure

52. There will be no parliamentary procedure for the publication of guidance. It would be unusual for there to be parliamentary scrutiny of this type of statutory guidance. The Department considers that it will be a sufficient safeguard that any guidance which, for example, steps outside the bounds of being genuinely about the discharge of the Triple Aim duty, will be amenable to judicial review. A further safeguard is that NHS England will be obliged, under the new section 13NB(2), to consult any persons it considers appropriate, prior to publishing or revising guidance.

Clause 7 , inserting new section 13YB(1) into the 2006 Act Exercise of functions relating to provision of services – power for NHS England by direction to provide for "relevant functions" to be exercised by one or more ICB
Power conferred on: NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

53. To reflect the more integrated approach to the commissioning and provision of health services that the Bill creates, this clause allows NHS England to determine that certain "relevant functions" should be carried out by local ICBs, instead of at a national / NHS England level.

54. These relevant functions fall into three categories:
    a. Commissioning functions under section 3B(1)
    b. Providing primary care services
    c. Public health functions

55. Functions that are ancillary to these functions (such as the ability to provide advice and assistance in relation to them) are also capable of being transferred.

Justification for taking the power

56. In order to be truly integrated as far as possible, ICBs need to also have responsibilities in relation to primary care. This power creates the mechanism by which NHS England's primary care functions can be delegated to the local ICB level.

57. In addition, in relation to certain commissioning functions and public health functions, NHS England may determine that ICBs are better placed to determine the needs of their populations and can therefore be given responsibilities in these areas where

appropriate.

58. The reasons this cannot be set out on the face of the Bill is that it will very much depend on the types of service, and the growing maturity of ICBs as to which services should be delegated from a national to a local level, and when.

59. Safeguards exist in the form of:
    a. Secretary of State regulations under s.13YB(3) can restrict the use of this power so that certain services cannot be delegated to ICB level (or only subject to certain conditions).
    b. The direction itself can block ICBs from using s.65Z5 to further delegate these functions to others (s.13YB(4)).
    c. The publication duty ensures transparency to the public in terms of where responsibility rests following the delegation (s.13YB(7).

Justification for the procedure

60. These directions require no Parliamentary procedure. This is consistent with the existing powers of direction in the 2006 Act.

Clause 7 - inserting new section 13YB(3) into the 2006 Act: Exercise of functions relating to provision of services – power for the Secretary of State by regulations to impose limitations or conditions on the power at new section 13Y(1)
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

61. To reflect the more integrated approach to the commissioning and provision of health services that the Bill creates, this clause allows NHS England to determine that certain "relevant functions" should be carried out by ICBs instead of at a national / NHS England level.

62. These relevant functions fall into three categories:
    a. Commissioning functions under section 3B(1)
    b. Providing primary care services
    c. Public health functions

63. Functions that are ancillary to these functions (such as the ability to provide advice and assistance in relation to them) are also capable of being transferred.

Justification for taking the power

64. Given the Secretary of State has overall responsibility for the health service, the power in subsection (3) affords an ability to set out, in regulations, any areas where it becomes apparent to the Secretary of State, that the appropriate body to carry out these functions

is NHS England; not ICBs. Alternatively, instead of preventing the delegation, restrictions or limitations can be placed upon it using this power.

Justification for the procedure

65. The Department considers the negative procedure would be proportionate and appropriate given the limited subject matter of these Regulations.

Clause 8(2) : Preparation of consolidated accounts for providers - inserting new section 65Z4 into the 2006 Act: power for the Secretary of State to direct NHS England as to the form and content of consolidated accounts
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

66. This clause gives the Secretary of State the power to direct NHS England as to the form and content of consolidated accounts which NHS England is under a duty to prepare in respect of NHS trusts and NHS foundations trusts annual accounts. The Secretary of State could also require NHS England to send the consolidated accounts, accompanied by such other reports and information as the Secretary of State may direct, to the Comptroller and Auditor General within time limits set by the Secretary of State in directions.

67. On receipt of any consolidated accounts, the Comptroller and Auditor General is to examine, certify and report on them and send a copy of the report to the Secretary of State and NHS England.

68. NHS England must lay a copy of the consolidated accounts and the Comptroller and Auditor General's report on them, before Parliament.

Justification for taking the power

69. These powers are currently delegated by way of directions in The Consolidated Provider Accounts Directions 2018, which are to be revoked. By transferring the delegated powers into the Bill, all that has changed is the body being directed. Previously, Monitor and the TDA were directed to provide consolidated accounts. Now, NHS England will be subject to this direction making power.

70. Accounting requirements need to be specified in detail and are likely to change over time (for example as the accounting rules and instructions set out by the Treasury in the annual Financial Reporting Manual are revised and updated), so it is not desirable to set them in primary legislation.

Justification for the procedure

71. The Department considers a Parliamentary procedure unnecessary for these directions. Accounting requirements for public bodies deal with technical matters and it is standard practice to use directions for this purpose (as with other bodies established under the 2006 Act). NHS England must lay copies of the consolidated accounts and the Comptroller and Auditor General's report on them, before Parliament, so Parliament can scrutinise the actual accounts rather than the process for preparing them.

Clause 9: Funding for service integration – power to direct NHS England that a given amount of its annual allotment be used for purposes relating to service integration
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

72. The Secretary of State may direct NHS England that a given amount of its annual allotment under 223B is to be used for purposes relating to service integration, and how this amount may be used. Where a direction is given, NHS England may direct an ICB that a given amount of the sums paid to it under section 223G in respect of that year is to be used for purposes relating to service integration.

73. The purpose of this proposed power is to preserve the ability for the Secretary of State to specify an amount of the annual allotment to NHS England that must be used for service integration that would be lost as a result of the policy to amend the provisions relating to the mandate to NHS England under section 13A. Currently the mandate is the mechanism by which the Secretary of State may require NHS England to ring-fence an amount of their annual allotment for service integration. Should there no longer be a duty to set a mandate annually, the Secretary of State will need an alternative power to determine an amount of the annual allotment to NHS England that it must use for service integration. This power is intended to preserve that ability, and provide that the Secretary of State may direct NHS England as to that amount for service integration, rather than include a requirement in the mandate that specified the amount.

Justification for taking the power

74. The power would be necessary to continue to enable the Secretary of State to specify an amount of NHS England's annual allotment which must be used for service integration, which would be lost by removing the duty to publish the mandate, including objectives and requirements, to NHS England annually. If Parliament were to set the limits in advance at the time of the passage of this Bill, it would not produce the most favourable outcome, and it would put additional pressures on parliamentary time to amend primary legislation to alter the limits.

75. This power is to be used at the Secretary of State's discretion.

Justification for the procedure

76. These directions do not require full Parliamentary scrutiny, however the Secretary of State must publish any direction pursuant to section 5(c). This would be appropriate given their content, which is an amount of money that NHS England must ring-fence for service integration purposes from the total amount allotted to them annually. This is also consistent with usual practice and there is precedent for making directions without procedure throughout the 2006 Act (see section 273 (4)).

Clause 9 - inserting new section 223GA into the 2006 Act: Expenditure on integration
Power conferred on: NHS England
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

77. Where the Secretary of State has given a direction under section 223B(6) to NHS England (that a given amount of its annual allotment under 223B is to be used for purposes relating to service integration), amended section 223GA (1) then provides that NHS England may direct an ICB that an amount of the sums paid to the board under 223G in respect of that year is to be used for service integration.

78. Section 223GA(1) is substituted with an amended version that provides the power for NHS England to direct an ICB and is available where the Secretary of State has given a direction under 223B(6).

79. The purpose of this proposed power is to preserve the ability for NHS England to specify an amount of the sums paid to ICBs that must be used for service integration. Given that the mandate process will no longer be the mechanism for the Secretary of State to specify sums for service integration, this section needed to be revised to reflect the new power.

Justification for taking the power

80. The power is necessary to continue to enable NHS England to direct ICBs that an amount of the sum paid to them under 223G must be used for service integration. If Parliament were to set the limits in advance at the time of the passage of this Bill it would not produce the most favourable outcome, and it would put additional pressures on parliamentary time to amend primary legislation to alter the limits.

Justification for the procedure

81. The Department do not consider that any Parliamentary procedure is necessary, as the directions will contain a designated amount of an annual allotment, administrative in nature.

Clause 11 – secondments to NHS England - Amends section 272 of the 2006 Act (orders, regulations, rules and directions) and inserts paragraph 9A in Schedule A1 to the 2006 Act

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

82. This clause makes express provision in the 2006 Act for secondees to work in NHS England and in particular, on NHS England's board.

83. Paragraphs 3 and 13 of Schedule A1 to the 2006 Act prevented NHS England from seconding senior executives from other NHS bodies onto its board and delegating functions to those senior executives. In order to ensure that NHS England can appoint the most suitable candidates to executive roles, amendments have been made to those paragraphs of Schedule A1 and additional paragraphs. The amendment allows senior executives from specified health bodies, to be members of the NHS England board.

84. As the phrase 'secondments' and 'secondees' is added into the 2006 Act for the first time, it is important to make clear in Schedule A1 that secondments throughout NHS England, in addition to senior executive secondments, are allowed. Amendments have been made to reflect this.

85. The 2006 Act will contain references to employees of NHS England (it currently refers to employees of the NHS Commissioning Board/National Health Service Commissioning Board). The regulation making power allows the Secretary of State to make clear that any reference to an employee of NHS England includes persons seconded to NHS England.

Justification for taking the power

86. The key provisions in the 2006 Act referring to employees of (what will be) NHS England, have been identified and there is no immediate need to modify those references to make clear that those employee include secondees. However, the power ensures that the Department can amend other references to employees, if that proves necessary in order to ensure effective operation of the secondment arrangements throughout NHS England. This will ensure that flexibility can be exercised appropriately by NHS England and any inappropriate obstacles removed if necessary.

Justification for the procedure

87. The use of the affirmative procedure is considered appropriate as the power is a broad one as it allows the Secretary of State to determine that employees from any other organisation can be considered an employee of NHS England, and to amend primary legislation to reflect this.

ICBs

Clause 13 – Establishment of ICBs

88. This clause inserts into Part 2 of the 2006 Act a new Chapter A3, which contains the following delegated powers.

Clause 13 – inserting new Section 14Z25 into the 20016 Act - Duty to establish ICBs by order
Power conferred on: NHS England
Power exercised by: Order
Parliamentary procedure: None

Context and purpose

89. New section 14Z25 provides (in subsection (2)) a power for NHS England to establish, by order, ICBs.

90. NHS England have a duty under subsections (3) and (4) to ensure that ICBs cover the whole of England but do not coincide or overlap. Subsection (8) provides that an order establishing an ICB must provide for the constitution of the ICB, either by setting out the constitution in the order itself or by referring to it as another published document, and must be published.

Justification for taking the power

91. This power will allow NHS England to establish ICBs across England.

92. NHS England must publish a list of areas for which the initial ICBs are to be established under 14Z26(1). Once this list has been published, section 14Z26 of the Bill will require existing CCGs to consult any appropriate persons and propose the first constitution for each ICB. NHS England will then be under a duty to review and give effect to a proposed constitution unless it is inappropriate or the CCG has not carried out an appropriate consultation.

93. It is important that the views of existing CCGs are taken on board in this way because as they have existing operational experience in their relevant geographical areas and so this knowledge will be useful in establishing the initial ICBs. The Bill provides for this preparatory work that will need to be completed before ICBs can be formally established. This is why it is not possible to set out in this Bill what the boundaries and constitutions of ICBs should be.

94. An order made under 14Z25 can be amended or revoked by virtue of section 272(8). Any such amendment or revocation could be to amend the geographical area of an ICB, or to dissolve an ICB – provided the whole of England continued to be covered.
Section 14Z25(7) provides that NHS England must consult any ICB that is likely to be affected before amending or revoking an order.

Justification for the procedure

95. Section 272(2) of the 2006 Act provides that any power to make an order, rules or regulations is exercisable by statutory instrument, subject to exceptions listed in subsections (1) and (3). Orders that establish ICBs will be added to the list in subsection (1) so that section 272 does not apply to them. This means that an order made under this power will not be a statutory instrument and not subject to any parliamentary procedure.

96. The duty on NHS England to establish ICBs, the functions and duties conferred on ICBs and the requirement for ICBs to cover the whole of England are set out on the face of the Bill. Parliament's approval on those matters is sought through the primary legislation and so the orders made under this provision, to achieve those matters Parliament will have already sanctioned, are not thought to require a parliamentary procedure.

97. The establishment process for CCGs, the commissioning bodies that ICBs will replace, was not subject to any Parliamentary procedure. Whilst not entirely analogous, there are examples in the 2006 Act of health bodies making orders that have no parliamentary procedure. The powers in section 56A(4A), 57 and 57A allow Monitor to make provisions by order in relation to mergers, acquisitions and dissolutions of NHS foundation trusts. In addition, the Secretary of State has a power under section 66(2) to make an intervention order where they consider that a NHS trusts or SpHA is not performing its functions adequately or if there are significant failings. As with the power in this clause, an order made under section 66(2) is not a statutory instrument and is not laid or subject to any parliamentary procedure.

Clause 13 – inserting new Section 14Z25 into the 2006 Act - Duty to establish ICBs – regulation-making power
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

98. Section 14Z25 subsection (9) provides a power for the Secretary of State to provide, by regulations, the appointed day on and after which NHS England are under a duty to ensure that ICBs cover the whole of England. The appointed day also applies for the purpose of section 14Z27, which has the effect of abolishing any remaining CCGs.

Justification for taking the power

99. It is important that there are no gaps in the coverage of commissioning arrangements when CCGs are abolished. It is therefore desirable to have the flexibility provided by a delegated power for setting the appointed day referred to in subsection (4).

100. A delegated power to prescribe this date avoids the need to try to predict the date by which all of the necessary preparatory work in determining the area for each ICB and proposing constitutions for each ICB will have been completed.

Justification for the procedure

101. The Department consider that the negative procedure is appropriate. The effect of the regulations would be to commence the duty that Parliament will have already scrutinised, and abolish any remaining CCGs. This power is comparable to a commencement power, which are not normally subject to any parliamentary procedure.

Clause 13 – inserting new section 14Z26 into the 2006 Act - Process for establishing initial ICBs – power to publish guidance in relation to functions under this section
Power conferred on: NHS England
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

102. New section 14Z26 subsection (6) gives NHS England the power to publish guidance for CCGs about the exercise of their functions under this section. CCGs, as described in relation to the power above, must consult with anyone they think appropriate and propose an initial constitution of the first ICB to be established for an area.

103. This power would enable NHS England to issue guidance on possible consultees, the form and content of an initial constitution.

Justification for taking the power

104. The power would enable NHS England to provide guidance in an accessible format to ensure a smooth and efficient process for the administrative process of consulting on and proposing an initial constitution. It is appropriate for NHS England, rather than the Secretary of State, to issue guidance as under the proposals in the Bill it is NHS England who will be responsible for reviewing and giving effect to a proposed constitution by establishing an ICB.

Justification for the procedure

105. Given the procedural content of the guidance, no Parliamentary procedure is considered necessary. Other examples of guidance being used for such procedural matters can be found in section 14L(7) and 14U of the 2006 Act relating to guidance on the discharge of CCGs functions and duties.

Clause 13 – inserting new section 14Z28 into the 2006 Act - Transfer scheme in connection with ICBs
Power conferred on: NHS England
Power exercised by: Scheme

Parliamentary procedure: None

Context and purpose

106. New section 14Z28 gives NHS England the power to make a transfer scheme in connection with;
    a) varying the constitution of an ICB by order under section 14Z25 or under provision included in its constitution by virtue of paragraph 144 of Schedule 1B
    b) the abolition of an ICB by order under section 14Z25
    c) the abolition of a CCG under section 14Z27

107. In such cases, NHS England can make transfer schemes, transferring any property, rights or liabilities (including criminal liabilities under 14Z28(4)(c)) from a CCG or an ICB to another ICB or NHS England. Transfer schemes provide a clear written record of the detail of any transfer, and this power is similar to existing powers in the 2006 Act, under which the Secretary of State can transfer property and liabilities.

108. Schedule 3 of the Bill makes amendments to the 2006 Act that will require ICBs to exercise functions in relation to the provision of primary care services. In connection with this, clause 18 confers on NHS England the power to make transfer schemes for the transfer of property, rights and liabilities to an ICB.

Justification for taking the power

109. Transfer schemes made using these powers are reliant on ICBs being established and they will be established after the relevant provisions in the Bill have come into force. For this reason, it would not be possible to provide for the transfer of property, rights or liabilities in the Bill and so this matter has been left to a delegated power.

Justification for the procedure

110. The Department considers a Parliamentary procedure unnecessary for the use of this power, since it would make provision for the property of individual CCGs and ICBs.

111. There is precedent for this approach: there is no procedure used in section 14I of the 2006 Act which allows NHS England to make a property transfer scheme or a staff transfer scheme in connection with the variation of a constitution of a CCG or the dissolution of a CCG. During the Bill's passage, Parliament will have the opportunity to consider the general principle behind the scheme and NHS England's ability to transfer property, rights and liabilities and so any schemes will be subject to the limitation placed on them by the Bill.

Clause 13 & paragraph 1 of Schedule 2 – regulation-making power in relation to ICB membership
Power conferred on: Secretary of State
Power exercised by: Regulation

Parliamentary procedure: Negative procedure

Context and purpose

112. Schedule 2 to this Bill inserts Schedule 1B into the 2006 Act. Part 1 of the new Schedule 1B sets out details relating to the constitution of an ICB.

113. Paragraph 9 of Schedule 1B provides that regulations may impose any requirements in connection with the membership of ICBs that must be complied with. The regulations may include requirements in relation to anything that must be included in the constitution, as provided for in paragraphs 3 to 8 of Schedule 1B. The information that must be included in the constitution under these paragraphs are:

    a) Membership (paragraph 3) – the constitution must provide for the ICB to consist of a chair, a chief executive officer and at least three other members
    b) Chair (paragraphs 4 and 5) – this paragraph requires the constitution to include provisions for the chair to be appointed by NHS England, with the approval of the Secretary of State. The constitution may not confer powers to remove the chair from office on any person other than NHS England, with the Secretary of State's approval.
    c) Chief executive (paragraph 6) – the constitution must provide for the chief executive to be appointed by the chair, with the approval of NHS England and that a person may only be the chief executive if they are an employee of the ICB.
    d) Ordinary members (paragraph 7) – this paragraph requires the constitution to specify who is to appoint the ordinary members, and provides that such appointment is subject to approval of the chair. Sub-paragraph (2) specifies who must be included as ordinary members and the constitution must set out the process for nominating these ordinary members.
    e) Further provisions in connection with membership (paragraph 8) – although not required, the constitution can include provisions on how members are to be appointed, the qualification and disqualification for membership, the tenure of members, eligibility for re-appointment, terms of appointment and the validation of proceedings in the event of a vacancy or defect in an appointment.

Justification for taking the power

114. The technical nature of this power and the level of detail any regulations made under this power would contain make it inappropriate to set in primary legislation.

Justification for the procedure

115. Regulations made under this section will be subject to the negative resolution procedure. The Department considers that this is appropriate as it will provide a degree of Parliamentary oversight, whilst ensuring that the details of the regulations can be updated to reflect developing policy on issues such as the nomination process for ordinary members of an ICB or disqualification criteria for such membership. Regulations made under this power will set out administrative details relating to ICB

constitutions and so are unlikely to be controversial, but Parliament has the opportunity to debate the matters if necessary.

Para 7 of new Schedule 1B – power to make regulations about ICB ordinary members
Power conferred on: Secretary of State
Power exercised by: Regulation
Parliamentary procedure: Negative procedure

Context and purpose

116. Paragraph 7 of new Schedule 1B makes provision about the ordinary members that must be appointed to an ICB. The constitution must provide for the ordinary members to include;
    a. one member nominated jointly by the NHS trusts and NHS foundation trusts that provide services within the ICB area – and are of a prescribed description,
    b. one member nominated jointly by persons who provide primary medical services for the purposes of the health service within the ICB area – and are of a prescribed description, and
    c. one member nominated jointly by the local authorities whose areas coincide with the ICB area.

Justification for taking the power

117. A delegated power is necessary to enable to Department the flexibility to update, from time to time, the descriptions of the nominating bodies to reflect developing local systems and new operating models of different providers.

Justification for the procedure

118. Regulations made under this section will be subject to the negative procedure. This is considered appropriate due to the technical nature of their subject matter.

Para 18 of new Schedule 1B – regulation making power in relation to ICB staff
Power conferred on: Secretary of State
Power exercised by: Regulation
Parliamentary procedure: Affirmative procedure

Context and purpose

119. Paragraph 17 and 18 of new Schedule 1B makes provisions about staff of ICBs. Paragraph 18 provides that an ICB may make arrangements for a person to be seconded to an ICB to serve as a member of the board's staff.

120. Paragraph 18(3) provide that in paragraphs 10 and 17 (provisions about arrangements for the discharge of an ICB's functions and staff of an ICB) a reference to an employee of an ICB includes a person seconded to the board.

121. Paragraph 18(4) of Schedule 1B provides that a reference to an employee of an ICB in paragraph 6(2) (the requirement that the chief executive of an ICB must be an employee of the board) includes any persons seconded to the ICB that is listed in (4)(a) and (b)(i) to (x).

122. Sub-paragraph (5) provides the Secretary of State with a power to amend the paragraph to provide that other references in the 2006 Act to an employee of an ICB include persons seconded to the board.

Justification for taking the power

123. The necessary references in the 2006 Act to employees of ICB (in new Schedule 1B), are listed in to paragraph 18 to ensure that reference to employee includes a person seconded to an ICB. However, the power ensures that the Department can amend other references to employees, if that proves necessary in order to ensure effective operation of the secondment arrangements.

Justification for the procedure

124. The use of the affirmative procedure is considered appropriate as the power enables the Secretary of State to amend primary legislation to update the list in sub-paragraph (4).

Para 21 of new Schedule 1B – directions in relation to ICB accounts
Power conferred on: NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

125. Paragraph 21 of new Schedule 1B makes provisions about the annual accounts that an ICB must keep. Each ICB is under a duty to prepare annual accounts in respect of each financial year.

126. Sub-paragraph (2) gives NHS England, with the approval of the Secretary of State, a power to direct an ICB to prepare accounts in respect of a specified period.

127. Sub-paragraph (4) gives NHS England, with the approval of the Secretary of State, a power to direct an ICB as to the methods and principles, form and content of any accounts prepared under this paragraph.

128. Sub-paragraph (6) provides that any accounts prepared under sub-paragraph (3) are to be audited if NHS England so directs.

129. Sub-paragraph (9) provides that NHS England may direct and ICB to send any unaudited accounts by a date specified.

130. These powers are likely to be used to assess the financial governance of an ICB and allow NHS England to carry out their national oversight role effectively.

Justification for taking the power

131. Delegated powers are thought necessary as NHS England will not always need to direct an ICB in relation to the matters above. It is likely that the power would only need to be used in relation to one ICB at a time and in circumstances where NHS England think it is necessary to do so.

Justification for the procedure

132. The Department consider that no Parliamentary procedure is necessary for directions given under this paragraph. Accounting requirements for public bodies deal with technical matters and it is standard practice to use directions for this purpose (as with other bodies established under the NHS Act 2006). in nature. This follows the approach in paragraph 17 of Schedule 1 to the 2006 Act that contains similar powers in relation to CCGs.

Clause 14: People for whom ICBs have responsibility

133. This clause inserts new section 14Z31 into Part A3 of the 2006 Act, after section 14Z30.

Clause 14 – inserting new section 14Z31 into the 2006 Act: People for whom ICB has responsibility – publication of rules determining the people for whom each ICB has core responsibility
Power conferred on: NHS England
Power exercised by: Rules
Parliamentary procedure: None

Context and purpose

134. Clause 14(2) inserts new section 14Z31(1) which provides that NHS England must publish rules determining the people for whom each ICB has core responsibility. Subsection (2) provides that these rules must ensure that everyone who is provided with NHS primary medical services and everyone who usually lives in England and is not provided with NHS primary medical services is allocated to at least one group.

135. The intention is to give NHS England the flexibility to determine who an ICB will have responsibility for commissioning services for.

Justification for taking the power

136. The policy intention is for ICB responsibility to be based on the lists of registered patients of primary care providers who provide services in the area of an ICB. This would ensure consistency with existing CCG responsibility as currently for CCGs, each primary care provider must be a member of a CCG. The ICB governance model differs from that of

CCGs, and primary care providers will no longer be members, so a different mechanism is needed to be able to associate primary care providers to an ICB. The rules will also enable NHS England to assign patients of primary care providers to one or more ICBs, where that primary care provider provides services in more than one ICB area.

137. The rules that NHS England must publish are intended to be framed in a way so as to assign the patients of certain primary care providers to an ICB, as well as anyone who usually resides in the area of an ICB but is not registered with any primary care provider. There is also a need for flexibility so that amendments can be made in the future to reflect changes to primary medical service providers, such as closures or new practices opening, which cannot wait for primary legislation to be made.

Justification for the procedure

138. The Department do not consider any parliamentary procedure is necessary, as the main principles that the rules must follow are set out in the primary legislation by subsection (2), which ensures that every person provided with NHS primary medical services and everyone usually resident in England is allocated to an ICB, subject to regulations made under subsection (3). The rules made under this section will address which people each ICB is responsible for, and may need to be amended from time to time to reflect changes in the details of those allocations.

Clause 14 – inserting new section 14Z31 into the 2006 Act: People for whom ICB has responsibility – regulation making power in relation to rules under this section
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

139. Under new section 14Z31 subsection (3), regulations may provide that the rules published by NHS England under subsection (2) do not apply to people of a prescribed description. The effect of such regulations would be that ICBs would not have responsibility for certain people or cases that would otherwise meet the criteria in the rules. This is intended to replicate the ability to make exceptions to the responsibility of CCGs by regulations in section 3(1D) of the 2006 Act.

Justification for taking the power

140. This power recreates the ability in section 3(1D) of the 2006 Act, and delegating the power avoids the need to set out in primary legislation detailed provisions about which groups of people should be excluded from the starting position on ICB responsibility, which could be subject to change from time to time.

Justification for the procedure

141. The Department consider that the affirmative procedure is appropriate, since this offers Parliamentary oversight whilst ensuring details of the regulations can be readily kept up to date. The affirmative procedure is consistent with the procedure for the current power to create exceptions for clinical commissioning group responsibility in section 3(1D) of the NHS Act 2006

Clause 14 – inserting new section 14Z31 into the 2006 Act: People for whom ICB has responsibility – regulation making power in relation to substitution of alternative versions of section 14Z31
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

142. Clause 14 (4) provides a power that enables the Secretary of State to substitute an alternative version of new section 14Z31 by regulations.

Justification for taking the power

143. The Bill includes a power to impose an alternative approach to determining responsibility of ICBs, which could be implemented at some point after the other proposals in the Bill have commenced. The alternative approach is simply that an ICB is responsible for everyone that usually reside within that area. This alternative approach would remove the ability for NHS England to publish rules that determine responsibility of ICBs, and fix the position.

Justification for the procedure

144. The Department consider that the negative procedure is appropriate. The effect of the regulations would be that the people for whom each ICB is responsible is determined differently, but it continue to provide that one or another ICB must be responsible for everyone who is usually resident in England. The details of which ICB is responsible for which individuals is administrative and technical in nature.

Clause 14 – inserting new section 14Z31 into the 2006 Act: People for whom ICB has responsibility – regulation making power in relation to this new section
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

145. Under the alternative version of new section 14Z31, that may be substituted by regulations referred to above, subsection (2) provides regulations may create exceptions that provide subsection (1) does not apply in relation to people of a

prescribed description. The effect of such regulations would be that ICBs would not have responsibility for certain people or cases that are otherwise usually resident in the area of the ICB. This is intended to replicate the ability to make exceptions to the responsibility of CCGs by regulations in section 3(1D) of the 2006 Act.

Justification for taking the power

146. This power recreates the ability in section 3(1D) of the 2006 Act, and delegating the power avoids the need to set out in primary legislation detailed provisions about which groups of people should be excluded from the starting position on ICB responsibility, which could be subject to change.

Justification for the procedure

147. The Department consider that the affirmative procedure is appropriate, since this offers Parliamentary oversight whilst ensuring details of the regulations can be readily kept up to date. The affirmative procedure is consistent with the procedure for the current power to create exceptions for clinical commissioning group responsibility, in section 3(1D) of the NHS Act 2006.

ICBs: functions

Clause 15: Commissioning hospital and other health services
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

148. This clause substitutes new section 3 and 3A into the 2006 Act and contains the following delegated powers.

Context and purpose

149. Section 3 of the 2006 Act places a duty on ICBs to arrange for the provision of health services listed to the extent it is necessary to meet the requirements of the people for whom it has responsibility. Section 3A is a power conferred on ICBs to arrange for the provision of other services or facilities as it thinks appropriate to secure improvements in the physical and mental health of the people for whom it is responsible, and in the prevention, diagnosis and treatment of illness in those people.

150. New section 14Z31 and the rules published under that section by NHS England provide the groups of people for whom each ICB is responsible for commissioning the services listed under substituted section 3(1). Subsection (2) of section 3 provides that for the purposes of section 3, the Secretary of State may prescribe, by regulations, additional people for whom an ICB has responsibility. Similarly, subsection (2) of section 3A provides that for the purposes of section 3A, the Secretary of State may prescribe, by regulations, additional persons for whom an ICB has responsibility.
151. This power to expand the scope of responsibility for ICBs is intended to recreate the power to make regulations under section 3(1B) of the 2006 Act. It is intended that this power will be used to cover certain specified situations, which might be a requirement for an ICB to arrange for necessary emergency care for anyone present in its geographical area, irrespective of whether they are normally the responsibility of another ICB in accordance with the rules published under 14Z31.

Justification for taking the power

152.

153.

Justification for taking the procedure

154.

Clause 16 and paragraphs 3, 15 and 27 of Schedule 3: Commissioning primary care services etc. – regulation making power to specify what services are regarded as primary medical services, primary dental services and primary ophthalmic services for the purpose of the 2006 Act
Power conferred on: Secretary of State

Power exercised by: Regulation
Parliamentary procedure: Negative procedure

Context and purpose

155. Currently, NHS England is under a statutory duty to exercise its powers so as to secure the provision of primary medical services, primary dental services and primary ophthalmic services to meet the requirements of the people it has responsibility for. The intention is to place a duty on ICBs to exercise their powers in a way that secures the provision of these primary care services for the people they will have responsibility for.

156. This clause will insert new sections 82A, 98C and 114C into the 2006 Act that will confer on the Secretary of State the power to make regulations that specify what services are to be regarded as primary medical services, primary dental services and primary ophthalmic services for the purposes of the 2006 Act.

Justification for taking the power

157. These powers simply restate existing powers in sections 83, 99 and 115 and do not alter the procedure that applies to them. The services that are classed as primary care services may vary over time and so this power allows the Secretary of State to react to any such changes to ensure that these services are provided by ICBs. This allows flexibility and ensures that there is adequate provision of primary care services.

Justification for the procedure

158. As explained above, this does not confer new powers on the Secretary of State but retains their existing powers. The negative procedure is currently used when any such regulations are made and the Department considers that this remains appropriate. During the Bill's passage, Parliament will have the opportunity to consider the substance of the duties being place on ICBs in relation to the provision of primary care services and any regulations made using these powers will only ensure that relevant services are included in this.

Clause 16 and paragraphs 6, 18 and 33 of Schedule 3 : Commissioning primary care services etc
Power conferred on: Secretary of State
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

159. The 2006 Act allows NHS England to enter into various contracts for the purposes of providing various primary medical services, these are:
    a) General medical services contracts ("GMS contracts") under section 84 for the purposes of providing primary medical services. Further provisions on GMS contracts are set out in sections 84 to 90 of the 2006 Act.

b) General dental services contracts ("GDS contracts") under section 100 for the purposes of providing primary dental services. Further provisions on GDS contracts are set out in sections 101 to 105 of the 2006 Act.
c) General ophthalmic services contracts ("GOS contracts") under section 117 for the purposes of providing primary ophthalmic services. Further provisions on GOS contracts are set out in sections 118 to 122 of the 2006 Act.

160. The Bill proposes to amend the current provisions on GMS contracts, GDS contracts and GOS contracts so that ICBs will also be able to enter into these contracts. The Secretary of State currently has a power to make directions in relation to payments made under these contracts and can specify that payments are only payable subject to certain conditions. One example of how this is currently used is in the General Ophthalmic Services Contracts (Continuing Education and Training Allowances) Payments Directions[1]. These directions have been given annually by the Secretary of State and they set conditions that ophthalmic practitioners must meet in order for the Board (now called NHS England under the Bill) to pay them an allowance for education and training in that year. As ICBs will also be able to enter into these contracts, they would also be subject to such directions.

Justification for taking the power

161. These amendments will not delegate further powers to the Secretary of State but instead extends their existing powers so that ICBs, as well as NHS England, can be subject to directions in relation to payments made under GMS, GDS and GOS contracts. This is necessary as ICBs will, under the new arrangements, be able to enter into these contracts, whereas previously only NHS England could do so. Before making any directions under these powers, the Secretary of State must consult any body who represents those who the payment in the direction relates to and any other person they consider appropriate. This places an important safeguard on the use of the power.

Justification for the procedure

162. No parliamentary procedure applies to the existing powers and this is considered to remain appropriate given the directions would deal with non-contentious administrative details. It is not considered necessary to require Parliamentary scrutiny and use up Parliamentary time. However, there is a consultation requirement which will add further transparency.

Clause 16 and paragraphs 8, 20 and 36 of Schedule 3 : Commissioning primary care services etc – regulation making power in relation to health care professionals
Power conferred on: Secretary of State
Power exercised by: Regulation
Parliamentary procedure: No

Context and purpose

[1] General ophthalmic service continuing education and training payment: 2021 - GOV.UK (www.gov.uk)

163. The Secretary of State has powers in sections 91, 106 and 123 of the 2006 Act to make regulations providing that health care professionals of a specified description cannot perform any primary medical, dental or ophthalmic services that NHS England is responsible for, unless they are included in a list maintained under the regulations by NHS England. These sections will be amended so that the regulations can also specify health care professionals that cannot perform any primary care services that ICBs are responsible for, unless they are included in the list maintained by NHS England.

Justification for taking the power

164. These amendments will not confer any new powers on the Secretary of State but amends their existing power. Currently, the Secretary of State can prevent specified health care professionals from performing primary medical services that NHS England are responsible for. As ICBs will also be responsible for providing primary care services, it is necessary for this power to be amended so that the health care professionals specified in the regulations cannot perform services ICBs are responsible for. The health care professionals that may be excluded from performing primary medical services may change over time and so the flexibility of secondary legislation is required.

Justification for the procedure

165. The negative procedure is currently used when exercising the powers in sections 91, 106 and 123 of the 2006 Act. The Department considers that this procedure remains appropriate. The general principle that the Secretary of State should be able to exclude certain health care professionals will have been considered by Parliament during the Bill's passage. It may be necessary to quickly add a category of professionals to the maintained list to ensure patient safety and effective regulation so primary legislation would be inappropriate.

Clause 16 and paragraphs 13, 25 and 38 of Schedule 3 : Commissioning primary care services etc – regulation making power in relation to the requirement to consult committees when exercising primary care services
Power conferred on: Secretary of State
Power exercised by: Regulation
Parliamentary procedure: Negative procedure

Context and purpose

166. The Secretary of State has existing powers in sections 97(6), 113(6) and 125(7) of the 2006 Act to make regulations that require NHS England to consult with Local Medical Committees, Local Dental Committees and Local Optical Committees when exercising their functions in relation to primary care services.

167. This clause will amend these sections so that ICBs will replace NHS England's functions in relation to the various committees and so can be subject to the existing regulation making power that can require them to consult the committees when exercising their functions in relation to primary care services.

Justification for taking the power

168. These clauses amend the current powers conferred on the Secretary of State meaning that, if regulations are made, they will impose the requirement to consult on prescribed matters on ICBs instead of NHS England. It is not considered necessary to require ICBs to consult the committees when they are exercising all of their functions in relation to primary care services, however, this power allows the Secretary of State to impose this requirement if a situation arises where this is deemed necessary.

Justification for the procedure

169. The negative procedure currently applies to any regulations made under sections 97, 113 and 125 of the 2006 Act and this remains appropriate. The only change to the powers will be that the regulations will apply to ICBs, rather than NHS England. This is ultimately a somewhat narrow power since it simply enables the Secretary of State to require ICBs to consult the committees in question, rather than requiring a certain outcome in the exercise of the ICB's functions.

Clause 16 and paragraphs 7, 19 and 35 of Schedule 3 : Commissioning primary care services etc. – regulation making power that provides for what is to be included in GMS, GDS and GOS contracts
Power conferred on: Secretary of State
Power exercised by: Regulation
Parliamentary procedure: Negative procedure

Context and purpose

170. Sections 89, 104 and 121 of the 2006 Act allow the Secretary of State to make regulations that provide for what is to be included in GMS, GDS and GOS contracts. As ICBs will be able to enter into these contracts, they must have regard to any such regulations.

Justification for taking the power

171. The Secretary of State currently has a regulation making power to prescribe what must be included in GMS, GDS and GOS contracts and this amendment widens the power as ICBs, as well as NHS England, must have regard to any such regulations.

Justification for the procedure

172. The Department considers the negative procedure remains appropriate when regulations are made using these powers given the subject matter covered.

Clause 16 and paragraphs 9-11 of Schedule 3 : Commissioning primary care services etc. – regulation making power in relation to section 92 of the 2006 Act

Power conferred on: Secretary of State
Power exercised by: Regulation
Parliamentary procedure: Negative procedure

Context and purpose

173. Currently under section 92 of the 2006 Act, NHS England can make agreements, other than the agreements provided for in section 83(2) or GMS contracts, for the provision of primary medical services. Any agreement made under this subsection must comply with regulations made under section 94. Regulations made by the Secretary of State under section 94 must ensure that parties, other than NHS England can withdraw from section 92 arrangements. These regulations can also make other provisions in relation to section 92 arrangements, such as the circumstances where such agreements can be made, the services they can cover and require details of the arrangements to be published.

174. This clause makes amendments so that ICBs can also make section 92 arrangements.

Justification for taking the power

175. The Department considers it appropriate to leave this matter to delegated legislation as the provisions in the regulations will vary depending on what the section 92 agreements cover and so the regulations will need to be adapted to cover the different nature of the arrangements. As ICBs will also be able to make section 92 agreements, it is necessary to amend the power so that ICBs come within their scope.

176. This power remains narrow as NHS England and ICBs can only enter section 92 agreements with the limited number of people and bodies that are listed in section 93(1).

Justification for the procedure

177. The negative procedure currently applies to regulations made under this power and this is still considered to offer sufficient Parliamentary scrutiny. The proposed amendments will bring ICBs within the scope of regulations and the power is not widened in any other way.

Clause 16 and paragraph 14 of Schedule 3 : Commissioning primary care services etc. – power to direct NHS England to exercise any of the Secretary of State's functions in relation to primary care, other than functions of making orders or regulations
Power conferred on: Secretary of State and NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

178. This clause will remove section 98A of the 2006 Act that currently permits the Secretary of State to give directions to NHS England on the exercise of their functions in relation

to primary care services. In addition, this section allows NHS England to direct ICBs on the exercise of their functions in relation to primary care services. This will be replaced with similar powers in relation to ICBs in new sections 98A to 98C.

179. The Secretary of State will retain his power to direct NHS England to exercise any of his functions in relation to primary care, other than functions of making orders or regulations. The new section 98B confers a direction making power on NHS England that will allow them to direct an ICB about the exercise of any of its functions.

Justification for taking the power

180. The direction making power given to NHS England replicates that which they currently have in relation to CCGs.

181. The Department considers it appropriate to leave this matter to secondary legislation as the functions will vary and so the need for flexibility is important.

Justification for the procedure

182. No Parliamentary procedure is considered necessary as the power is about who performs a function in a particular circumstance. This is viewed by the Department as an administrative arrangement under the supervision of the Secretary of State. The principle of the nature of any function subject to such a direction is not changed and will have been sanctioned by Parliament as those functions are set out in the primary legislation.

Clause 16 and paragraph 26 of Schedule 3 : Commissioning primary care services etc. – power to direct an ICB about the exercise by it of any of its functions
Power conferred on: Secretary of State and NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

183. This clause removes section 114A of the 2006 Act that allows the Secretary of State to give directions to NHS England to exercise any of his functions relating to the provision of primary dental services. This will be replaced by new sections 114A and 114B in the new section 114A, the Secretary of State will retain the power to direct NHS England to exercise any of his functions relating to the provision of primary dental services, other than those relating to the making of an order or regulations.

184. Section 114B gives NHS England the power to direct an ICB about the exercise by it of any of its functions.

Justification for taking the power

185. The directions made under this power will vary depending on which of the ICBs functions are being addressed and so there is a need for flexibility. Similarly, the

functions, which will be subject to this power, are not known from the outset so it is not practicable to include this in the Bill.

Justification for the procedure

186. The direction making power conferred on NHS England by this clause replicates that which they already have in relation to CCGs and the Department still considers that no Parliamentary procedure is needed for this matter.

Clause 16 and paragraph 39 of Schedule 3 : Commissioning primary care services etc. – power to direct an ICB about the exercise by it of any of the board's primary ophthalmic functions
Power conferred on: Secretary of State and NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

187. This clause will remove section 125A of the 2006 Act and replace this with new sections 125A and 125B. The current section 125A gives the Secretary of State the power to give directions to NHS England to exercise any of their functions in relation to the provision of primary ophthalmic services, other than those relating to making orders and regulations. The newly inserted sections contain a similar power and also confers direction making powers on NHS England.

188. Section 125B gives NHS England the power to direct an ICB about the exercise by it of any of the board's primary ophthalmic functions.

Justification for taking the power

189. This matter has been left to delegated legislation as the functions that NHS England will direct ICBs to exercise will vary depending on the circumstances at the time and so a greater deal of flexibility is required. The power has been narrowed as some prescribed functions can be excluded from this power. In addition, NHS England can provide ICB with information to assist them in carrying out functions that have been delegated by directions and ICBs must report to NHS England on matters arising out of the exercise of any of these functions.

Justification for the procedure

190. No Parliamentary procedure is considered necessary for directions made using this power. This is a similar power to the one NHS England currently have through section 125A of the 2006 Act to direct CCGs, SpHA and such other boards that may be prescribed. The proposed power is slightly narrower than the one currently available as directions can only be given to ICBs, and not other bodies.

Clause 16 and paragraph 40 of Schedule 3: amends section 168A of 2006 Act – delegation of Secretary of State's functions to NHS England

Power conferred on: Secretary of State
Power exercised by: Direction
Parliamentary procedure: No procedure

191. New section 168A(1) and (2) are simply restatements of the existing section168A(1) and (2) but just with "the Board" being replaced with a reference to its new name: "NHS England". Existing section 168A(3) has not been restated in the new section168A because its effect is already captured by new section 13ZC (Secretary of State directions as to exercise of NHS England functions) which is inserted by clause 37.

Clause*Power conferred on: NHS England*
Power exercised by: Scheme
Parliamentary procedure: None
Context and purpose

193.

194.

195.
Justification for taking the power

Justification for the procedure

197. The Department considers a Parliamentary procedure unnecessary for the use of this power, since it would make provision for the property, rights and liabilities of NHS England to ICBs.

198. There is precedent for this approach: there is no procedure used in section 14I of the 2006 Act which allows NHS England to make a property transfer scheme or a staff transfer scheme in connection with the variation of a constitution of a CCG or the dissolution of a CCG.

Clause 19: General functions – inserting new section 14Z45 into the 2006 Act: Joint exercise of functions with Local Health Boards – regulation making power for any prescribed functions of an ICB to be exercised jointly with a Local Health Board
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative procedure

Context and purpose

199. This clause inserts new section 14Z45 into the 2006 Act. It allows regulations to be made providing for any prescribed functions of an ICB to be exercised jointly with a Local Health Board. The regulations can also provide that, where functions are exercised jointly, they can be exercised by a joint committee of the ICB and the Local Health Board.

Justification for taking the power

200. Currently, regulations can be made under section 14Z4 of the 2006 Act that provide for any prescribed functions of a CCG to be exercised jointly with a Local Health Board and Parliament scrutinised this power when passing the 2012 Act. This clause simply mirrors the current provision of 14Z4 but, as ICBs will replace CCGs, the power applies to ICBs and Local Health Boards.

Justification for the procedure

201. The proposed power is akin to that in section 14Z4 of the 2006 Act, which is subject to the negative procedure. The Department considers this procedure remains appropriate as the power is limited and only recreates the power currently provided for in the 2006 Act in relation to CCGs. Parliament will have the opportunity during the Bill's passage to scrutinise the range of functions conferred on ICBs and the ability to exercise functions jointly in this way.

Clause 19 – inserting new section 14Z48 into the 2006 Act - Responsibility for payments to providers – power to publish a document under this section
Power conferred on: NHS England
Power exercised by: Document
Parliamentary procedure: None

Context and purpose

202. This clause inserts new section 14Z48 into the 2006 Act which gives NHS England the power to publish a document, under subsection (1), specifying circumstances in which an ICB is liable to make payments to a provider for services provided under arrangements commissioned by another ICB.

203. The general position is that an ICB is responsible for commissioning services for the people for whom it is responsible under new section 14Z31. It follows that if an ICB has legal responsibility for commissioning a service, that ICB is also legally responsible for payment for that service.

204. There are some exceptions to this, which might include an ability for NHS England to specify that where a person uses an urgent care service commissioned by an ICB other than the one that is ordinarily responsible for that person's healthcare, the cost of that service is to be charged to the latter ICB.

205. If NHS England publish a document under this section, ICBs are required to make the payments in accordance with that document.

Justification for taking the power

206. Taking a delegated power to enable NHS England to make the specification described above allows NHS England to set out details of any arrangements and to update or amend those details if changes are required. NHS England has the equivalent power to publish a document in section 14Z7 of the 2006 Act in relation to CCGs responsibility for payments to providers. This clause provides the same powers, but applies to ICBs instead of CCGs.

Justification for the procedure

207. Since the power is concerned with operational and administrative matters that relate to the responsibility of an ICB to make payments for service provided in pursuance of arrangements made by another ICB, a Parliamentary procedure is considered unnecessary.

Clause 19 – inserting new section 14Z48 into the 2006 Act - Responsibility for payments to providers – power for NHS England to publish guidance for ICBs
Power conferred on: NHS England
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

208. New section 14Z48 subsection (6) provides a power for NHS England to publish guidance for ICBs to assist with understanding and applying a document published under subsection (1).

Justification for taking the power

209. Taking a delegated power to enable NHS England to publish guidance on the application of a document published under subsection (1) allows NHS England to keep the guidance up to date in line with the document. It is appropriate for NHS England to have this power, as it is NHS England that is responsible for ensuring ICBs work together effectively to arrange for services.

Justification for the procedure

210. As is usual for guidance, and given it relates to a duty that is set out in the Bill and is likely to be detailed, a Parliamentary procedure is considered unnecessary.

Clause 19 – inserting new section 14Z49 into the 2006 Act: Guidance by NHS England
Power conferred on: NHS England
Power exercised by: Guidance

Parliamentary procedure: None

Context and purpose

211. New section 14Z49 confers a duty on NHS England to publish guidance for ICBs on the discharge of their functions.

Justification for taking the power

212. A power to issue guidance is considered appropriate as it allows information to be provided for ICBs in an accessible format that can be kept up to date without waiting for primary legislation. It is also expected that guidance under this section will be extensive. It is appropriate for NHS England to publish statutory guidance for ICBs, as they will have the national oversight role for ICBs.

Justification for the procedure

213. As is usual no Parliamentary procedure is considered necessary for guidance under this section: its content will be operational and administrative, assisting ICBs in the discharge of their functions conferred by the Bill.

Clause 19 – inserting new Section 14Z50 into the 2006 Act: Joint forward plans for an ICB and its partners
Power conferred on: NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

214. This clause also inserts new section 14Z50 which requires each ICB and their partner NHS trusts and NHS foundation trusts, before the start of each financial year, to prepare a joint forward plan setting out how they propose to exercise their functions in the next five years. Subsection (4) requires the ICB and its partner NHS trusts and NHS foundation trusts to give a copy of the plan to each relevant integrated care partnership, each relevant Health and Wellbeing Board and NHS England.

215. Subsection (5) confers a power on NHS England to direct an ICB and its partner trusts the date by which subsection (4) has to be complied with, the requirement to give a copy of the plan to the bodies mentioned above.

Justification for taking the power

216. This power has been left to delegated legislation as the date NHS England wish to specify may vary from year to year, but also it may not always be necessary for NHS England to specify a date under subsection (5).

Justification for the procedure

217. The Department consider that this power should not be subject to any Parliamentary procedure. This is considered appropriate as the power can only be used to require the date by which a plan is received, and is considered a non-contentious and administrative matter.

Clause 19 – inserting new Section 14Z54 into the 2006 Act: Joint capital resource use plan for an ICB and its partners – power to direct the period to which a capital resource use plan must relate to
Power conferred on: Secretary of State
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

218. New section 14Z54 requires each ICB and their partner NHS trusts and NHS foundation trusts, before the start of each financial year, to prepare a joint capital resource use plan. Subsection (2) enables the Secretary of State to specify, by direction, the period to which a plan under this section must relate. The Secretary of State must publish any direction given under subsection (2).

Justification for taking the power

219. This power has been left to delegated legislation as the period for which a spending review relates may change for time to time and as such the capital resource use plans prepared under this section should be capable of relating to a period that aligns with the Departmental capital limits.

Justification for the procedure

220. The Department consider that this power should not be subject to any Parliamentary procedure, as Parliament will set the capital resources available to the NHS and for what period. Any directions made under this section will enable the capital planning for local areas to reflect those decisions.

Clause 19 – inserting new Section 14Z54 into the 2006 Act: Joint capital resource use plan for an ICB and its partners – power to direct an ICB and its partner trusts the date by which a copy of the plan must be provided
Power conferred on: NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

221. Subsection (5) requires the ICB and its partner NHS trusts and NHS foundation trusts to give a copy of the plan to each relevant integrated care partnership, each relevant Health and Wellbeing Board and NHS England.

222. Subsection (6) confers a power on NHS England to direct an ICB and its partner trusts the date by which subsection (5) has to be complied with, the requirement to give a copy of the plan to the bodies mentioned above.

Justification for taking the power

223. This power has been left to delegated legislation as it may not be necessary for NHS England to specify a date under subsection (6). In addition, the date NHS England specify as needing the plans may vary.

Justification for the procedure

224. The Department considers that this power should not be subject to any Parliamentary procedure. This is considered appropriate as the power can only be used to require the date by which a plan is received, the requirement to prepare and publish the plan will be scrutinised during the Bill's passage.

Clause 19 – inserting new Section 14Z54 into the 2006 Act: Joint capital resource use plan for an ICB and its partners – power to publish guidance about the discharge of functions under this section
Power conferred on: NHS England
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

225. Subsection (7) provides a power for NHS England to publish guidance about the discharge of functions under this section by an ICB and its partner NHS trusts and NHS foundation trusts.

Justification for taking the power

226. A delegated power to produce guidance allows the information on how the ICBs and partner NHS trusts and NHS foundation trusts to be provided in an accessible format and more easily kept up to date.

Justification for the procedure

227. The Department considers that this power should not be subject to any Parliamentary procedure. This guidance published under this section would be operational and administrative, assisting the bodies with how to discharge the duty imposed by this section.

Clause 19 – inserting new section 14Z56 into the 2006 Act: Annual report – power to make directions specifying the form and content of an annual report under this section
Power conferred on: NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

228. This clause also inserts new section 14Z56 into the 2006 Act requiring ICBs to prepare an annual report on how it has discharged its functions in the previous financial year. Subsection (4) gives NHS England the power to make directions specifying the form and content of an annual report under this section.

Justification for taking the power

229. Delegating the power in section 14Z56 allows NHS England to set detailed requirements for the annual report that would not be appropriate to include in primary legislation. Furthermore, it may not be necessary for NHS England to specify the form and content of an annual report, however, this power provides that option if necessary. The Department considers that directions may need to be given under this power to ensure annual reports prepared by each ICB are consistent in form and content to enable NHS England to have adequate oversight over the performance of each ICB.

230. NHS England currently have a similar power in section 14Z51 of the 2006 Act and can give directions to CCGs on the form and content of the annual report that they are required to prepare under that section.

Justification for the procedure

231. The Department considers that the form and content of the annual report relates to administrative requirements in relation to the report and so it is not necessary for this to be subject to a Parliamentary procedure.

Clause 19 – inserting new Section 14Z59 into the 2006 Act: Power to give directions to ICBs – power to direct an ICB to discharge the functions that they have failed to do so, in a manner and time period which will be specified in the directions
Power conferred on: NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

232. New section 14Z59 provides various direction making powers to NHS England if they are satisfied that an ICB is failing or has failed to discharge any of its functions or there is a significant risk of this. For this purpose, a failure to discharge a function includes a

failure to discharge it properly, and this can occur where NHS England consider the function has not been discharged consistently with the interests of the health service.

233. Subsection (2) gives NHS England the power to direct an ICB to discharge the functions that they have failed to do so, in a manner and time period which will be specified in the directions.

234. Subsection (3)(a) gives NHS England the power to direct an ICB, and (3)(b) the power to direct the chief executive of an ICB, to cease performing the functions that they have failed to discharge for a time period which can be specified in the direction.

235. Subsection (4) gives NHS England the power to terminate the appointment of an ICB's chief executive and give a direction as to which individual to appoint as a replacement.

236. Where a direction is given under subsection (3)(a), subsection (5)(b) enables NHS England to direct another ICB to perform the functions on behalf of the failing ICB. Where a direction is given under (3)(b), subsection (6)(b) enables NHS England to direct the chief executive of another ICB to perform the functions of the chief executive that must cease to perform functions.

237. Subsection (7) requires NHS England to consult the ICB or chief executive to whom it is proposing to give a direction under (5)(b) or (6)(b).

Justification for taking the power

238. These powers will only be necessary where ICBs are failing, have failed, or there is a significant risk of, an ICB failing to discharge their functions. As the failure of an ICB to perform any of its functions may have serious consequences for patients and the health service generally, it is not possible to create a limited category of functions, the failure to perform which, would give rise to NHS England having power to make a direction under this section.

239. As the types of potential failure, and consequences of them, are wide, it is appropriate tor NHSE to have the discretion to give directions as to the manner in which the function should be exercised in order to remedy the failure. In addition, the powers provided will not be needed if ICBs discharge their functions correctly and so there may be no need for the exercise of this power.

240. The intervention powers proposed may need to be exercised in a timely fashion in order to efficiently remedy a situation where an ICB is failing to discharge their functions and primary legislation would not be appropriate in such circumstances.

241. NHS England currently have a similar power in relation to CCGs in section 14Z21 of the 2006 Act. This allows them to give directions to CCGs or the accountable officer of the group to perform specified functions or cease to perform any functions where the CCG has failed, or there is a significant risk of failing, to discharge any of its functions. Similar to the power in this clause, section 14Z21 then allows NHS England to carry out the functions that are subject to a direction, or direct another CCG to carry out the functions.

Justification for the procedure

242. No Parliamentary procedure is considered necessary to use the proposed intervention powers in this clause. It is important that this power can be used without delay. This follows the current intervention power NHS England have in section 14Z21 in relation to CCGs that are failing to discharge their functions

Integrated care partnerships

Context and purpose

243. Section 116 of the Local Government and Public Involvement in Health Act 2007 places a duty on local authorities to prepare an assessment of relevant needs in relation to the area they have responsibility for. A relevant need for this purpose is where it appears there is a need:

    a) which is capable of being met to a significant extent by a local authority exercising its functions and could also by met, or otherwise affected, by CCGs or NHS England exercising any of their functions; or

    b) Which is capable of being met to a significant extent by CCGs or NHS England exercising any of their functions and could also be met, or otherwise affected, by the local authority exercising any of its functions

244. It is the responsibility of local authorities and their partners to prepare any assessment and, as CCGs are being replaced, ICBs will take over this responsibility. Subsection (2) provides that the Secretary of State can direct a further relevant needs assessment to be prepared in relation to an area of each responsible local authority. This clause makes amendments to subsections (6) to (9) that will require ICBs to prepare this assessment, with the responsible local authority, by substituting references to CCGs for ICBs.

Justification for taking the power

245. Further relevant needs assessments are supplemental to relevant needs assessments that are required under section 116 of the 2007 Act. Therefore, it is not always required for a further relevant needs assessment to be produce but this power gives the Secretary of State the ability to direct that such an assessment takes place . This is not a new power but amends the Secretary of States power so that CCGs are replaced by ICBs as one of local authorities' partners for this purpose.

Justification for the procedure

246. This clause does not confer new powers but makes amendments to reflect that CCGs are being removed and ICBs are being established. As this change will not widen the power, the Department considers it remains appropriate to have no Parliamentary procedure for this matter.

Integrated care system: financial controls

247.

Context and purpose

248.

249.

250.

Justification for taking the power

251. Delegated powers are needed in this section because the requirements as to what is or is not to be taken into account for the purposes of various financial limits are likely to be detailed and subject to change from time to time.

Justification for the procedure

252. The Department considers a Parliamentary procedure unnecessary, given the administrative content of the directions. This equivalent existing powers in existing section 223C of the 2006 Act are not subject to any Parliamentary procedure.

Clause 21 – inserting

Context and purpose

253.

254.

Justification for taking the power

255. This delegated power is needed so that the Government can ensure, if necessary, that the allocations to NHS England are held in Government Banking accounts until sums are paid out.

Justification for the procedure

256. The Department considers a Parliamentary procedure unnecessary, given the administrative content of the directions. This position is the same for the equivalent existing powers that this section recreates.

Context and purpose

257.

258.

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Justification for taking the power

261. This delegated power is necessary because the Secretary of State should have the ability to amend the amounts of the limits specified from year to year, to reflect the resource limits that the Department must operate within.

Justification for the procedure

262. The Department considers a Parliamentary procedure unnecessary, given the administrative content of the directions, but transparency around limits being set will be maintained through the requirement to publish and lay before Parliament any directions made under this section.

Context and purpose

263.

264.

265.

Justification for taking the power

266. This delegated power is necessary because the Secretary of State may need to impose additional controls on resource use from time to time, for example to ensure that the Department does not exceed the limit set by Treasury, in line with Government commitments.

267. The limits on administrative costs and on resource use that would be imposed under this new section, and the detailed specification relating to them, would be likely to change from time to time, so would be unsuitable for primary legislation.

Justification for the procedure

268. The Department considers a Parliamentary procedure unnecessary, as the directions would deal with financial details. This position is the same for the equivalent existing powers in section 223E that this section recreates.

Clause 23: Financial responsibilities of ICBs and their partners

269. This clause inserts new sections 223GB to 223GD and contains the following delegated powers.

Clause 23 – inserting new section 223GB into the 2006 Act: Power to impose financial requirements on ICBs
Power conferred on: NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

270. This clause inserts new section 223GB into the 2006 Act and will allow NHS England to direct ICBs in relation to their management or use of financial or other resources. Subsection (2) provides that any direction made under this power can impose limits on expenditure or resource use by an ICB. The directions can apply to ICBs generally, or to ICBs of a particular description.

271. Under subsection (3) NHS England must publish any directions given under this section.

Justification for taking the power

272. Taking a delegated power is necessary in order to have the flexibility to impose specify bespoke limits on the expenditure or resource use that may differ between ICBs and differ from year to year. It would not be possible to pre-empt any limits that may be necessary to impose in primary legislation.

Justification for the procedure

273. The Department considers that no Parliamentary procedure is necessary as the directions are operational in nature and suit the medium of directions. This allows NHS England to respond quickly to changing individual needs of ICBs. NHS England is required to publish any directions under this section under subsection (3) to ensure further transparency.

Clause 23 – inserting new section 223GC into the 2006 Act: Financial duties of ICBs: expenditure limits
Power conferred on: NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

274. The new section 223GC(1) places a duty on ICBs to exercise functions with a view to ensuring that expenditure incurred by the board in a financial year does not exceed the sums received by it in that year.

275. Subsection (2)(a) provides NHS England with a power to specify, by directions, descriptions of expenditure that are not to be treated as expenditure incurred by an ICB generally, or in relation to a particular financial year, for the purpose of the duty in subsection (1).

276. Subsection (2)(b) provides NHS England with a power to specify descriptions of sums that should or should not be treated as having been received by an ICB generally or in a financial year.

277. Subsection (2)(c) provides NHS England with a power to provide, by directions, that sums received by an ICB in a year under section 223G but are not spent, are to be treated as expenditure incurred in a particular financial year.

Justification for taking the power

278. Taking a delegated power is necessary in order to provide the required level of detail as to what will be taken into account in determining whether an ICB remains within its expenditure limits. These details are subject to change and may require updating year to year and would not be appropriate for inclusion in primary legislation and are administrative in nature and so best suited to directions.

Justification for the procedure

279. The Department considers that no Parliamentary procedure is necessary. The directions would deal with non-contentious financial details and so do not appear to require Parliamentary scrutiny.

Clause 23 - inserting new section 223GD into the 2006 Act – power to make directions requiring ICB to use specified banking facilities

Power conferred on: Secretary of State
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

280. The new section 223GD confers on the Secretary of State the power to make directions requiring an ICB to use specified banking facilities for specified purpose that would be provided for in the directions. This could be used to require an ICB to use the Government banking service, rather than open a commercial bank account. This takes account of the Treasury requirement that all NHS money is held in Government banking service accounts, where it offsets the national debt.

Justification for taking the power

281. It may not always be necessary to direct an ICB to use a specified banking facility, so taking a delegated power offers the necessary flexibility. The Secretary of State

currently has an equivalent power to require CCGs to use specified banking facilities in the current section 223H(3) of the 2006 Act. This clause seeks to mirror this power in relation to ICBs.

Justification for the procedure

282. No Parliamentary procedure is proposed for these directions due to purely the administrative nature of the subject matter. This is in line with the current section 223H(3) of the 2006 Act.

Clause 23: Financial responsibilities of ICBs and their partners, inserting new section 223L into the 2006 Act – power to set joint financial objectives for ICBs etc.
Power conferred on: NHS England
Power exercised by: Setting an Objective
Parliamentary procedure: None

Context and purpose

283. This clause inserts new section 223L into the 2006 Act. This will allow NHS England to set joint financial objectives for ICBs and their partner NHS trusts and NHS foundation trusts. Where such financial objectives are set, ICBs and their partner trusts must seek to achieve them.

Justification for taking the power

284. This has been left to delegated legislation as the subject of any joint financial objectives will vary depending on the ICB and partner NHS trusts and NHS foundation trusts in question and the financial situation at the time. This means that the flexibility of secondary legislation is necessary.

Justification for the procedure

285. No parliamentary procedure is proposed. The directions would deal with non-contentious financial details and it is not considered necessary to require Parliamentary scrutiny.

Clause 23: Financial responsibilities of ICBs and their partners, inserting new section 223N to the 2006 Act – power of direction on the use of resources
Power conferred on: NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

286. This clause will insert a new section 223N. Subsection (1) provides that ICBs and its partner NHS trusts and NHS foundation trusts must:

a) Exercise their functions with a view to ensure that they do not exceed the local capital resource limit that NHS England may specify in directions. For this purpose, local capital resource use is the use of capital resources by an ICB and its partner NHS trusts and NHS foundation trusts.
b) Exercise their functions with a view to ensure that they do not exceed the local revenue resource limit that NHS England may specify in a direction. For this purpose, local revenue resource use is the use of revenue resources by the ICB and its partner NHS trusts and NHS foundation trusts.

287. Section 223N(3) provides that where an NHS trust or NHS foundation trust is a partner to more than one ICB, NHS England can give a direction to apportion its use of resources between one or more of its partner ICBs.

288. Section 223N(4) gives NHS England the power to, by directions, make provision for determining to which ICB, trust, or foundation trust a use of capital resources or revenue resources is to be attributed for the purposes of 223N.

Justification for taking the power

289. The powers in this section will need to be used flexibly to deal with different limits for local systems. It is also necessary to be able to make different provision for each local system as not all NHS trusts or NHS foundation trusts will be partner to more than one ICB, so apportionment will not be necessary in all areas. A delegated power will enable NHS England to specify local resource use limits that reflect local healthcare needs and other circumstances that may arise in each area.

Justification for the procedure

290. No parliamentary procedure is proposed. The directions would deal with non-contentious financial details and relate to individual situations and it is not considered necessary to require Parliamentary scrutiny.

Clause 23: Financial responsibilities of ICBs and their partners, inserting new section 223O to the 2006 Act – power of direction in relation to additional controls on resource use
Power conferred on: NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

291. This clause inserts new section 223O into the 2006 Act that contains provisions on additional controls of resource use by ICBs and its partner NHS trusts and NHS foundation trusts.

292. Section 223O(1)(a) gives NHS England the power to direct an ICB and its partner NHS trusts and NHS foundation trusts to exercise their functions with a view to ensuring that

their local capital resource use (same meaning as in section 223N) which is attributable to matters specified in a direction does not exceed a set amount.

293. Section 223O(1)(b) contains a similar power in relation to the local revenue resource use by an ICB and its partners. NHS England may make directions specifying an amount that is attributable to certain matters does not exceed a set amount in relation the use of local revenue resource.

294. For the purposes of subsection (1), NHS England can give directions specifying uses of capital resources or revenue resources that are, or are not, to be taken into account for the relevant limits.

Justification for taking the power

295. Currently, the direction making powers conferred on NHS England in the equivalent section 223J help to create CCG financial accountability. The amended powers are necessary to ensure that similar financial controls and accountability are placed on ICBs and their partner trusts so that financial limits are not exceeded. A delegated power is necessary as the limits are likely to change from year to year and may be different between each local area based on the resources that are available to that system.

Justification for the procedure

296. No parliamentary procedure is proposed. The directions would deal with non-contentious financial details and it is not considered necessary to require Parliamentary scrutiny for such operational provisions.

Clause 23: Financial responsibilities of ICBs and their partners, inserting new section 223P to the 2006 Act – power to give directions that specify descriptions of resource or use of capital and revenue resource relevant to section 223D, 223E or 223N
Power conferred on: Secretary of State
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

297. This clause inserts new section 223P into the 2006 Act. This confers on the Secretary of State the power to give directions that specify descriptions of resources or use of capital and revenue resources that must, or must not, be taken into account for the purposes of sections 223D, 223E, 223N of the 2006 Act.

Justification for taking the power

298. The resources and use of these resources that can be specified in directions are likely to vary and so flexibility is important for the use of this power meaning that primary

legislation would be inappropriate and the technical and operational details is best suited to directions.

Justification for procedure

299. It is not proposed that directions under this section will be subject parliamentary procedure. The directions would deal with non-contentious financial and operational details and it is not considered necessary to require Parliamentary scrutiny.

Clause 24 : Expansion of financial duties of ICBs and their partners, inserting section 223LA to the 2006 Act – power to direct ICBs in relation to their expenditure duty
Power conferred on: NHS England
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

300. This clause inserts new section 223LA, that may be commenced at a later date than the rest of the Bill, to have the effect of expanding the ICB expenditure duty.

301. The Department has the ability, through this provision, to expand the duty on expenditure limits so that an ICB and their partner NHS trusts and NHS foundation trusts must exercise their functions with a view to ensuring that their expenditure in a financial year (taken together) does not exceed the aggregate of the sums received by them in that year. Adding providers into this duty at a later date will enable the Department to account for system expenditure, taking together ICB and partner trusts as the intended mutual responsibility between NHS bodies in a local area develops.

302. It is intended that this provision be brought into force at some point after commencement to replace section 223C. Subsection (3)

Justification for taking the power

303. Delegated powers are needed in this section because the requirements as to what is or is not to be taken into account for the purposes of various financial limits are likely to be detailed and subject to change from time to time.

Justification for the procedure

304. The Department consider a Parliamentary procedure unnecessary, given the administrative content of the directions. Any directions made would give further details to what Parliament has already agreed NHS England should have the power to do.

Merger of NHS bodies etc.

Clause 31: Transfer schemes in connection with abolished bodies – power to create schemes
Power conferred on: Secretary of State
Power exercised by: Scheme
Parliamentary procedure: None

Context and purpose

305. Upon the abolition of Monitor and the National Health Service TDA and the transfer of their functions to NHS England, it will be necessary for property, rights and liabilities held by the former bodies to be transferred to the latter.

Justification for taking the power

306. The most appropriate vehicle for effecting these transfers will be a statutory transfer scheme, as is commonly used in similar situations involving transfers of assets following transfers of functions between public bodies. It would not be feasible to deal with the detail of all of the necessary transfers of property, rights and liabilities on the face of the Bill.

Justification for the procedure

307. As is generally the case with statutory transfer schemes, there is no parliamentary procedure for the schemes.

Clause 32 :Transfer schemes under section 31: taxation – power to make regulations in relation to tax pertaining to the transfer scheme

Power conferred on: The Treasury
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

308. Clause 33 provides that the Treasury may vary the way in which a relevant tax has effect in relation to—
    a. anything transferred under a scheme under section 31, or
    b. anything done for the purposes of, or in relation to, a transfer under such a scheme.

Justification for taking the power

309. The Department's intention is that any transfer of assets, rights, or liabilities be tax neutral for the transferee and the transferor. In order to ensure that no taxes arise, and no changes to the tax position of either the transferee or transferor body arise, the Bill includes a power to vary any relevant tax.

Justification for the procedure

310. As this power is only intended to be used for the purpose of ensuring that the effect of any transfer is tax neutral, it is not considered necessary that there be significant parliamentary scrutiny of any variations in tax under this power. Indeed the power will need to be used relatively rarely as health service bodies are exempt from many forms of taxation in any event. Therefore, the Department considers the negative procedure would be proportionate and appropriate.

Secretary of State's functions

Clause 35 : Power of direction: public health functions, inserting a new section 7B into the 2006 Act – power to direct relevant bodies to exercise functions in relation to public health

Power conferred on: Secretary of State
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

311. Pursuant to existing legislation under section 7A of the 2006 Act, the arrangements for the delegated exercise of the Secretary of State's public health functions are restricted to those that can be made *by agreement* only. The Secretary of State's "public health functions" are functions under section 2A (duty to take steps to protect public health), section 2B (power to take steps to improve public health) or certain functions under Schedule 1.

312. NHS England currently commissions a range of services which include national immunisation and screening programmes negotiated through the annual NHS Public Health Functions Agreement with the Secretary of State. The Secretary of State cannot *require* NHS England, or any other NHS body to take on a delegated public health function. This potentially exposes him to a position whereby he is unable to effectively deliver an aspect of his public health duties. In particular, his duty to secure improvement in the physical and mental health of the people of England and in the prevention, diagnosis and treatment of physical and mental illness under section 1 of the 2006 Act[2] for example due to delays and protracted negotiations on the terms of a delegation agreement and he is forced to find other means of complying in order to satisfy his duty to act.[3]

313. The proposal is therefore to create a power for the Secretary of State to require NHS England (or an ICB) to discharge public health functions delegated by the Secretary of State, *via the making of directions*.

314. This proposed power of direction for public health is intended to provide for greater speed, agility, certainty and clarity to keep in step with challenges presented to public health. The pandemic has demonstrated the need to respond to public health issues and shown acting promptly and without delay is paramount.

315. Clause 35 inserts a new section 7B into the 2006 Act, providing the Secretary of State with a broad delegated power to direct a relevant body (defined as NHS England or an ICB) to exercise by itself or jointly any of the Secretary of State's public health functions. Where a direction provides for NHS England to exercise a function, NHS England may

[2] The right under section 3a of the NHS Constitution "to receive the vaccinations that the Joint Committee on Vaccination and Immunisation recommends that you should receive under an NHS provided national immunisation programme" is also of relevance here.
[3] In the case of local government, the 2006 Act provides an alternative mechanism to s.7A via s.6C regulations.

arrange for onward delegation so that the function may be exercised by, or jointly, with one or more ICBs or combined authorities.

316. The new section 7B(3) provides that a direction may prohibit or restrict a relevant body from making arrangements under new sections 65Z5 (joint working and delegation arrangements) and 65Z6 (joint committees and pooled funds). This ensures that any functions that should not be capable of being delegated can be prescribed and protected and any functions that may be delegated but that need to be more closely controlled can be subject to conditions.

Justification for taking the power

317. The power is designed to strengthen the overall accountability of the Secretary of State by providing him with the means to discharge his duties under the 2006 Act. In particular, his duty to secure improvement in the physical and mental health of the people of England and in the prevention, diagnosis and treatment of physical and mental illness under section 1 of the 2006 Act. This direction making power therefore empowers the Secretary of State where he considers it appropriate to set direction and to better influence the prioritisation of public health functions in a transparent manner.

318. It is appropriate that the Secretary of State has this flexibility to direct in order to adequately respond to public health issues and secure provision of services more quickly. The power is intended to be consistent with other existing direction making powers and other new powers proposed in the Bill. The intention of the power is that it will strengthen the Secretary of State's ability to play the role in the system that Parliament expects of him/ her by removing obstacles to the delivery of public health functions by other bodies.

319. It is expected that the delegation of public health functions will continue working on the basis of agreement in most circumstances. However, consistent with other changes in the Bill, it is considered appropriate to adopt an approach which enhances the Secretary of State's ability, via the flexibility of a direction making power, to ensure the system can respond rapidly to emerging issues as they arise, or where the additional clarity and certainty of directions is otherwise desirable.

320. This matter has been left to delegated legislation because it would be very difficult to set out all the ways in which it could be used in primary legislation.

Justification for the procedure

321. The power is intended to be consistent with other existing direction making powers in the Bill. In keeping with the approach to the direction making model they require no Parliamentary procedure. This is consistent with the existing powers of direction in the 2006 Act. To ensure transparency, the Secretary of State will need to provide directions in writing, stating that he is satisfied that they are in the public interest, and to publish these as soon as is practicable.

Clause 36 : Power of direction: investigation functions, inserts sections 7C and 7D into the 2006 Act – power to direct NHSE England or any other public body to exercise any of the investigation functions, previously exercised by TDA
Power conferred on: Secretary of State
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

322. This clause gives the Secretary of State the power to direct NHS England or any other public body to exercise any of the investigation functions which had been previously exercised by the National Health Service Trust Development Authority (TDA). The TDA was directed to exercise those investigatory functions under two separate directions: the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 (the main investigatory functions) and the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018 (the maternity investigatory functions).

323. The TDA will be abolished and their directions revoked in this Bill. There will be a need for the investigatory functions carried out by the TDA to continue to be carried out by a body for a temporary period until such time when a more permanent solution is in place. For the main investigatory functions, that permanent solution will be HSSIB once it is established by provisions in this Bill.

324. The power of direction will be the vehicle through which the main investigatory functions and the maternity investigatory functions will be exercised by NHS England, or any other public body in the interim period.

Justification for taking the power

325. The Secretary of State has been directing the TDA to carry out investigatory functions. This power of direction simply changes the bodies who are now to be subject to the power of direction to carry out investigatory functions as a result of the abolition of the TDA, until a more permanent solution is available.

Justification for the procedure

326. The proposed power is a power of direction which is not subject to the Parliamentary procedure. This will give the Secretary of State the flexibility to move the investigatory functions to other bodies as soon as they are established and able to carry out those investigatory functions.

Clause 36 : Power of directions: investigation functions, inserts section 7E into the 2006 Act - power to make regulations in relation to tax pertaining to the transfer scheme under section 31
Power conferred on: The Treasury
Power exercised by: Regulations

Parliamentary procedure: Negative

Context and purpose

327. New section 7E provides that the Treasury may vary the way in which a relevant tax has effect in relation to—
    a. anything transferred under a scheme under section 31, or

    b. anything done for the purposes of, or in relation to, a transfer under such a scheme.

Justification for taking the power

328. The Department's intention is that any transfer of assets, rights, or liabilities be tax neutral for the transferee and the transferor. In order to ensure that no taxes arise, and no changes to the tax position of either the transferee or transferor body arise, the Department have been advised by HMRC that the transfer scheme provisions should include a power for the Treasury to vary any relevant tax.

Justification for the procedure

329. As this power is only intended to be used for the purpose of ensuring that the effect of any transfer is tax neutral, it is not considered necessary that there be significant parliamentary scrutiny of any variations in tax under this power. Indeed the power will need to be used relatively rarely as health service bodies are exempt from many forms of taxation in any event. Therefore, the Department considers the negative procedure would be proportionate and appropriate.

Clause 37 : General power to direct NHS England – power to direct NHS England as to the exercise of its functions
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

330. The Bill is going to merge NHS England, Monitor and the TDA to provide unified leadership for the NHS. NHS England will be responsible for spending £130bn (and rising) of taxpayers' money and for overseeing the NHS. In recognition of this merger and NHS England's expanded role, the Department is bringing forward this proposal to ensure the Secretary of State has appropriate intervention powers over NHS England.

331. Sections 13ZC, D, E and F provide the Secretary of State with a broad delegated power to direct NHSE in relation to its functions. In particular:
    - Section 13ZC enables the Secretary of State to direct NHS England as to its functions.

- Section 13ZD lists the exceptions where the Secretary of State cannot use 13ZC to direct NHS England.
- Section 13ZE enables the Secretary of State to discharge, or to arrange for someone else to discharge, NHS England's functions where NHS England has failed to comply with a direction and the Secretary of State considers that failing to be significant.
- Section 13ZF enables the Secretary of State to direct NHS England to provide information.

332. Clause 62 removes the duties of the Secretary of State and NHS England to promote autonomy under section 1D of the 2006 Act. This change has been made in recognition of the enhanced role that the Secretary to State now has over NHS England.

333. Clause 10 amends section 233K of the 2006 Act to remove subsections (4) and (5) which gives the Secretary of State the power to make regulations about payments by NHS England in respect of quality. NHS England's powers to make payments in respect of quality remain, and the new power of direction can be used should the Secretary of State consider it appropriate to intervene in this area.

Justification for taking the power

334. Existing accountability mechanisms including the statutory mandate to NHS England will remain the primary mechanism through which the Secretary of State will set out the objectives that NHS England should be seeking to achieve and any requirements that it must comply with in order to meet those objectives. However, in recognition of the expanded powers and responsibilities of NHS England, this provision seeks to introduce an additional intervention mechanism to support the Secretary of State in the democratic oversight of NHS England.

335. This matter has been left to delegated legislation because it enables flexibility. An example of a way in which it may be used is that the Secretary of State could use the powers to request to see guidance developed by NHS England before it is published to ensure NHS England is working effectively with other parts of the system (e.g. local authorities) and that the views other parts of the system are represented and aligned with such guidance.

336. This power is narrowed as follows:
    - The three exceptions provided for in section 13ZD
    - When exercising the power the Secretary of State will be obliged to act consistently with his general duties set out in the 2006 Act, in particular sections 1A – 1F, as well as general public law principles.
    - The Secretary of State could not direct NHS England to do anything which is unlawful or not to perform a duty.
    - The Secretary of State could not use this general power where there is a more specific power regulation making power in existence.

337. In terms of transparency, the Secretary of State will need to provide directions in writing, stating why they are in the public interest, and these will be published as soon as is

practicable. There already is close working between Ministers and NHS England and this power formalises this relationship.

Justification for the procedure

338. These directions require no Parliamentary procedure. This is consistent with current direction making powers in the 2006 Act.

Clause 38 and Schedule 6: Reconfiguration of services: intervention powers, inserting new Schedule 10A into the 2006 Act – intervention powers in relation to the reconfiguration of NHS services
Paragraph 4, Sch 10A- power to "call in" a reconfiguration
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

339. The new Schedule 10A to be inserted into the 2006 Act creates intervention powers over the reconfiguration of NHS services.

340. A reconfiguration of NHS services will be defined as a change in the arrangements made by an NHS commissioning body for the provision of NHS services where that change has an impact on:
    a. the manner in which a service is delivered to individuals (at the point when the service is received by users), or
    b. the range of health services available to individuals.

341. The NHS commissioning bodies will be NHS England and ICBs.

342. On occasions, there are NHS reconfigurations that give rise to significant cause for public concern and lead Ministers to assess that there is a critical benefit or cost to taking a particular course of action. There is currently a lack of formal mechanism that allows the Secretary of State to intervene and take a decision on a reconfiguration matter regardless of what stage in the process it is at.

343. The Secretary of State currently has a very limited ability to intervene in reconfigurations. Part 4 of the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013[4] ("the 2013 regulations") make provision for local authorities (or their Health Overview and Scrutiny Committee ("HOSC")) to review and scrutinise major changes to the provision of services in their area. A HOSC that does not support the proposal that a CCG has under consideration, or does not believe the consultation was adequate, can refer the proposal to the Secretary of State. The Secretary of State can then take a final decision on the matter referred, or make a direction to the Board, which may make a direction to a CCG.

[4] SI 2013/218

344. The Secretary of State can only take a final decision on reconfiguration proposals where a referral has been made to the Secretary of State by a HOSC. In all other circumstances the Secretary of State is unable to intervene, despite being politically responsible for the NHS to Parliament.

345. The HOSC referral regime also limits the ability of the Secretary of State to become involved in reconfigurations at an earlier stage to try to have input into a decision. The risk of doing so is that a final decision under the regulations may then be challenged as a result of perceived bias or pre-determining the outcome as a result of his earlier involvement.

346. This system also prevents the Secretary of State from calling a halt to a proposal that he thinks is not in the best interest of the health service, simply because a HOSC has not made a formal referral. This presents a disconnect between the Secretary of State's responsibility for the NHS publicly and to parliament, and his inability to intervene or take a decision where he thinks it is necessary.

347. These Bill provisions create a bespoke 'call in' power to allow Secretary of State to take a decision on a reconfiguration at any stage of the process.

348. It is proposed that there be a new duty placed on the NHS England, ICBs and NHS providers to notify the Secretary of State if there is a planned reconfiguration or circumstances that are likely to give rise to the need for a reconfiguration (paragraphs 2 and 3 of the new Schedule 10A).

349. It is proposed that a new discretionary power be created at (paragraph 4) that allows the Secretary of State to give a direction to an NHS body that a proposal for a reconfiguration be "called in". The effect of a reconfiguration being called in will be that the Secretary of State will have the power to make any decision in relation to the proposed reconfiguration that could have been made by the NHS commissioning body.

    This will include (paragraph 4(b)):

    The power to decide whether a proposal should, or should not, proceed, or should proceed in a modified form;

    a. power to decide particular results to be achieved by the NHS commissioning body in taking decisions in relation to the proposal;
    b. power to decide procedural or other steps that should, or should not, be taken in relation to the proposal;
    c. power to retake any decision previously taken by the NHS commissioning body.

350. NHS England, an ICB or an NHS provider who is subject to a direction from the Secretary of State under this section must refer the reconfiguration decision to the Secretary of State, provide all relevant information and take no further action in progressing the reconfiguration without the Secretary of State's agreement. They will be able to make representations to the Secretary of State in support of their preferred option at this stage.

Justification for taking the power

351. It would not be feasible for primary legislation to deal with the level of detail concerning NHS operations that falls to be considered when deciding upon NHS reconfigurations. Reconfigurations around the country happen frequently, and often at short notice, meaning it would not be practical to Parliament to determine the appropriate result regarding each reconfiguration in primary legislation.

Existing example of a call-in power

352. There is a precedent for a call-in power already on the statute book. Section 77 of the Town and Country Planning Act 1990 provides a similar power to the one this Bill proposes to create for the Secretary of State. Section 77 provides the Secretary of State a power to direct the local planning authority to refer an application to him for decision, which takes the decision making power away from the local planning authority. This is known as a "called in" application. The Secretary of State also has a power to give directions requiring the decision on a planning proposal to be delayed until he has decided whether or not to call-in an application.

Safeguards on the use of the power

353. Whilst it is recognised that the Secretary of State's discretion under this power will be wide, there will in practice be constraints on the use of the power. His scrutiny and direction making process must take into account the public law decision making principles, all relevant information and his legal duties, including the Public Sector Equality Duty. These checks and balances, along with the risk that any decision could be challenged, will help ensure decisions taken are rational, reasonable and based on all relevant considerations.

If the Secretary of State takes a decision such as a) above, the effect of a direction from the Secretary of State is that the NHS body would need to ensure that all of the proposals under consideration include the Secretary of State's precondition, e.g.retaining an A&E unit at the specified site. If the Secretary of State takes a decision such as b) above, the Secretary of State would direct the NHS body to include that option in the consultation and then proceed as normal. If the Secretary of State takes a decision such as c), the Secretary of State would direct the NHS body to take on the decision and implement that option.

Justification for the procedure

354. These powers relate to detailed operational matters and it would be usual practice for matters of this sort to be carried out through directions rather than regulations.

355. These directions require no Parliamentary procedure. This is consistent with current direction making powers in the 2006 Act.

Clause 38 and Schedule 6 : Reconfiguration of services: intervention powers, inserting new Schedule 10A into the 2006 Act – intervention powers in relation to the reconfiguration of NHS services

Paragraph 6, Sch 10A – power to direct an NHS commissioning body to consider a reconfiguration

Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

356. The Secretary of State should be able to exercise the call in power at any stage of a reconfiguration process, but also be able to be the catalyst for a reconfiguration where he thinks appropriate. This might occur before NHS England, an ICB or an NHS provider has notified the Secretary of State of a proposed reconfiguration but where the Secretary of State is aware of an emerging issue following stakeholders raising the issue with the Secretary of State or information from within the Department.

357. It is therefore proposed that the Secretary of State have the power to direct an NHS body to consider a reconfiguration of NHS services (paragraph 6 of Schedule 10A).

Justification for taking the power

358. This power is an important element of the Secretary of State's power to exercise appropriate influence over NHS reconfigurations, and enables him to act positively and proactively. Without it, and solely with the power in paragraph 4, he would only be able to influence the reconfiguration process when the NHS body decided to propose, or consider, a reconfiguration.

359. As with the power to "call in" reconfigurations, it would not be feasible for primary legislation to deal with the level of detail concerning NHS operations that falls to be considered when exercising this power. A need for a reconfiguration, and thus potentially for the Secretary of State to direct that one should be considered by the relevant NHS bodies, may arise at short notice. It would not be practical for Parliament to determine when a reconfiguration should be considered on each occasion.

Justification for the procedure

360. This power relates to detailed operational matters and it would be usual practice for matters of this sort to be carried out through directions rather than regulations.

361. These directions require no Parliamentary procedure. This is consistent with current direction making powers in the 2006 Act.

Clause 38 and Schedule : Reconfiguration of services: intervention powers, inserting new Schedule 10A into the 2006 Act – intervention powers in relation to the reconfiguration of NHS services

Paragraph 8, Schedule 10A
Power conferred on: Secretary of State
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

362. A new power to issue guidance on the call in process is also proposed. Guidance is intended to be used to set out the responsibilities of NHS England, ICBs, relevant NHS providers (NHS Trusts and Foundation Trusts) and the Secretary of State where a matter is called in setting out such matters as; timetables for decisions, how representations can be made and the details of how a decision made under the call in power should be implemented. NHS England, ICBs, and NHS providers will be under a duty to have regard to the guidance.

Justification for taking the power

363. It will be helpful for commissioning bodies, providers and stakeholders for the matters intended to be set out in the guidance, mentioned above, to be made publicly available. It will give them clarity in what to expect when a reconfiguration is called in, and their obligations under paragraph 10A in respect of providing information to the Secretary of State.

364. It would be impractical for Parliament to consider this level of operational detail.

Justification for the procedure

365. This power relates to detailed operational matters and it would be usual practice for matters of this sort to be set out in guidance.

366. The Department's view is that it would not be usual or proportionate for there to be parliamentary scrutiny of this type of statutory guidance.

NHS trusts

Clause 44 and clause 45 : Oversight and support of NHS trusts and Directions to NHS trusts, inserting new sections 27A and 27B into the 2006 Act - NHS England's advice, guidance and support to NHS trusts and NHS England's directions to NHS trusts
Power conferred on: NHS England
Power exercised by: Directions and guidance
Parliamentary procedure: None

Context and purpose

367. NHS England will now have functions conferred on it in respect of NHS trusts which were, and in some case cases remain, functions of the Secretary of State. NHS England will be both the regulator of NHS trusts and the provider of assistance and support to NHS trusts. Clause 44 will place NHS England under a duty to provide such advice, guidance or other support as it considers appropriate to help NHS trusts in England in the carrying out of their functions. Clause 45 confers on it a power to direct NHS trusts about the exercise of its functions. The Secretary of State will continue to have a power of direction over NHS trusts under section 8 of the 2006 Act. Under subsection (2), any direction made under section 27B by NHS England, will have no effect if it conflicts with a direction made by the Secretary of State. The scope of NHS England's power of direction is no wider than that conferred on the Secretary of State under section 8 of the 2006 Act.

Justification for taking the power

368. The duty on NHS England to provide guidance to NHS Trusts on the carrying out of their functions will provide helpful clarity to NHS Trusts about NHS England's expectations and in many cases may avoid the need for the power of direction to be used.

369. The Secretary of State has an existing power in the 2006 Act to direct NHS trusts and SpHA about their functions, neither of which are subject to any Parliamentary procedure or scrutiny. The power is currently also exercised by the TDA, a SpHA responsible for overseeing NHS trusts. The TDA is being abolished and in general its functions transferred under the Bill to NHS England. NHS England will have the function of overseeing and supporting NHS trusts so this is simply a continuation of the existing arrangement rather than a new power.

370. The power can be used for operational matters in relation to an individual NHS trust.

Justification for the procedure

371. These powers are not subject to Parliamentary procedure. It is standard for guidance of the type to be provided under clause 44 not to be subject to a Parliamentary procedure. Directions pursuant to clause 45 are likely to be used where the circumstances dictate

so cannot necessarily be predicated. The Department considers that this is appropriate as it allows NHS England to react quickly to any issues concerning the health and safety of patients.

Clause 48 :NHS trusts: conversion to NHS foundation trusts and dissolution – power to dissolve an NHSE trust by order

Power conferred on: NHS England
Power exercised by: Order
Parliamentary procedure: None

Context and purpose

372. NHS England will have the power to dissolve an NHS trust by order and only with the approval of the Secretary of State. NHS England may also make an order to transfer property and liabilities of the NHS trust to the Secretary of State or an NHS body. The dissolution process is triggered if an NHS trust applies for dissolution or the Secretary of State or NHS England consider that dissolution is appropriate in the interests of the health service.

373. Previously, only the Secretary of State held the power to dissolve an NHS trust. The TDA would assess proposals made by NHS trusts to be dissolved and to transfer property and liabilities. The TDA would then prepare a written report to the Secretary of State on whether an application for dissolution should be supported. The TDA would also make recommendations to the Secretary of State if, in its opinion, an NHS trust should be dissolved and should transfer property and liabilities.

374. As NHS England is taking on many of the TDA functions and will have all the relevant information to take decisions on whether NHS trusts should be dissolved, the Department has decided that NHS England should also have the power to dissolve NHS trusts, but only on the approval of the Secretary of State.

375. The Secretary of State is to retain the power to dissolve NHS trusts.

Justification for taking the power

376. This power amends the current provision where the Secretary of State can dissolve an NHS trust by way of an order. The amendment adds a further body, NHS England, who can dissolve an NHS trust by way of an order. This is consistent with the policy of allowing NHS England to take more decisions affecting the NHS where it has the information to do so, but under approval of the Secretary of State.

Justification for the procedure

377. This power relates to the administrative arrangements necessary to effect dissolution of an NHS trust. This could happen only with the approval of the Secretary of State. The

Department considers that no Parliamentary procedure is necessary as this is replicating an existing power where no Parliamentary procedure was required.

NHS foundation trusts

Clause 52 : Capital spending limits for NHS foundation trusts– power to impose a limit on capital expenditure of an NHS foundation trust
Power conferred on: NHS England
Power exercised by: Order
Parliamentary procedure: None

Context and purpose

378. NHS England may make an order imposing a limit on capital expenditure of any NHS foundation trust. This order must specify the trust, the capital expenditure limit and the period to which the limit related.

379. This proposed provision would allow NHS England to limit an NHS foundation trust's capital expenditure for a given time. Currently the Department is responsible for a prescribed amount of annual capital spending across the whole NHS, as per the Capital Departmental Expenditure Limit ("CDEL") set by Parliament. The Department has no legal means to influence the capital spending of NHS foundation trusts even though that spending falls within the CDEL 'envelope'. This can lead to delays in agreeing capital spending projects across the NHS where there is a degree of uncertainty and unpredictability associated with capital spending by NHS foundation trusts. As a result of this uncertainty, the Department may need to withhold or delay funding on capital projects elsewhere in the NHS in order to manage to overall CDEL position.

Justification for taking the power

380. Over the last few years NHS trust and NHS foundation trust plans have shown a significant increase in forecast capital expenditure. Should all of the funding planned for be spent, the NHS would breach the year's CDEL. There are existing powers that allow limits and controls to be set for capital expenditure by NHS trusts and by ICBs. Those existing powers do not currently apply to NHS foundation trusts. A power to limit the capital expenditure of individual NHS foundation trusts is necessary to allow the Department and the NHS to take a more co-ordinated approach to capital investment and to manage capital spend across the NHS. Potential breaches of CDEL present a significant issue for the Department and for the NHS as spending in excess of the national limit, which is voted on and authorised by Parliament, can result in sanctions and/or a tighter reporting regime.

381. NHS England is best placed to assess the forecasts for capital expenditure and determine the limit for relevant NHS foundation trusts. NHS England must consult with the NHS foundation trust before making any order and must publish the order.

Justification for the procedure

382. It is proposed that no procedure should apply to order made under clause j700. This is considered appropriate as the power is limited to setting capital expenditure limits on individual NHS foundation trusts to help the wider NHS stay within capital expenditure limits that have already been agreed by Parliament.

383. NHS England will work within the parameters outlined by the published guidance, which the Secretary of State will be consulted on. Parliament will be presented with the statutory instrument which makes the order,

384. This approach is consistent with existing practice and there is precedent for making orders without procedure throughout the Act (e.g. section 272(5)).

NHS trusts and NHS foundation trusts

Clause 58 : Transfer schemes between trusts – power to make transfer schemes
Power conferred on: NHS England
Power exercised by: Scheme
Parliamentary procedure: None

Context and purpose

385. As a result of this new clause, NHS England ("NHSE") may make one or more schemes for the transfer of property, rights and liabilities from a relevant NHS body to another relevant NHS body on an application made to it under this section.

386. The application must be made jointly by the relevant NHS bodies and state the property, rights or liabilities to be transferred.

387. A transfer scheme may amongst other things, create rights or impose liabilities in relation to property or rights transferred. It may make provision for shared ownership or use of property, make provisions about the continuing effect of things done by the transferor in respect of anything transferred etc.

388. The transfer scheme may provide for modifications by agreement.

Justification for taking the power

389. A delegated power is needed, as it would not be practical to make specific provision in primary legislation in each case where a transfer of property and staff, and of the associated rights and liabilities, proves to be necessary. As the national body responsible for oversight, NHS England will be best placed to determine what transfers are needed and will need powers to effect such transfers swiftly.

390. Further, delegating the power is necessary as the need for a transfer is a matter which depends on whether circumstances arise which make a scheme necessary. As such, this is not something that can be predicted in advance. There may be situations where a transfer of one or more sites and associate services from one NHS Trust or foundation trust to another was proposed because of commissioning changes, with the transferor retaining its other sites and associated services. Those commissioning changes cannot always be predicted in advance. This transfer scheme is necessary for example to assist with partial transfers which could take place after one NHS trust is dissolved and services are split between two other Trusts. Alternatively, the transfer scheme may be used to merge one trust into another and, as part of a two-stage process, transfer existing legacy from one trust to another. The schemes would be specific in nature and would be used in individual cases. Each scheme would apply only to the particular arrangement and particular property, rights and liabilities in the scheme. The details cannot therefore be set out in primary legislation.

Justification for the procedure

391. The transfer schemes are likely to include more technical detail than is normally included on the face of a Bill. As the schemes would be concerned with administrative and operational details, the Department considers that no Parliamentary procedure is required.

Clause 59 and Paragraph 7 of Schedule 8: amends section 65H of the 2006 Act on consultation requirements for trust special administrators
Power conferred on: Secretary of State and NHS England
Power exercised by: Directions
Parliamentary procedure: No procedure

Context and Purpose

392. This clause amends section 65H in Chapter 5A of the 2006 Act. Chapter 5A enables the Secretary of State to appoint a trust special administrator for trusts and foundation trusts where he deems it in the interests of the health service. At subsection (9A) there is a power of direction for NHS England to direct a trust special administrator to hold a meeting to seek a response from any person during the mandatory consultation process. Subsection (10) restates a direction making power of the Secretary of State to direct NHS England to direct trust special administrators as to requests for written response from any person and as to holding a meeting to seek a response from any person during that process.

Justification for taking the power

393. The provision of these powers is in recognition of the greater role NHS England has with regards to trust special administrators going forward. Directions will enable NHS England and the Secretary of State flexibility in responding to changing circumstances, for example when organisations change their name or structure.

Justification for the procedure

394. These powers of direction are likely to be technical and administrative in nature. These directions require no Parliamentary procedure. This is consistent with the existing powers of direction in the 2006 Act.

Joint working and delegation of functions

Clause 60 : Joint working and delegation arrangements – inserting new section 65Z5 into the 2006 Act – power, by regulations, to provide that relevant bodies' power to enter into joint working arrangements does not apply, applies to a prescribed extent, or applies subject to conditions.
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

395. Section 65Z5(1) provides that a relevant body may arrange for any functions exercisable by it to be exercised by or jointly with any one or more of the following:
    a) A relevant body;
    b) A local authority (within the meaning of section 2B)
    c) A combined authority.

396. Section 65Z5(2) specifies that the relevant bodies include:
    a) NHS England
    b) An Integrated Care Board
    c) An NHS Trust established under section 25
    d) An NHS Foundation Trust
    e) Such other body as may be prescribed.

397. Section 65Z5(3) provides that Regulations may (a) provide that the power in subsection (1) does not apply, or applies to a prescribed extent, in relation to prescribed functions or (b) impose conditions on the exercise of the power.

398. This ensures that any functions that should not delegated can be prescribed and protected and any functions that may be delegated but that need to be more closely controlled can be subject to conditions.

399. The new provisions amend the existing legislative framework to permit delegations (and permit delegations of a greater range of functions), subject to certain safeguards provided for in regulations.

Justification for taking the power

400. The delegated power provides flexibility to specify what functions may not be exercised jointly with or by another body or what functions can be exercised on behalf of, or jointly with another body. Delegating the power avoids the need to set out in primary legislation detailed provisions about the services to be provided and the groups to whom they must be provided.

401. The arrangements under these clauses enable new and different approaches to the exercise of functions, which would need to be reviewed and developed in a flexible manner as they could change over time. There are a wide range of delegable functions, carrying very different risks which might require different conditions. The Secretary of State having the power to make regulations allows for this flexibility and avoids the delay that would be caused by needing to pass primary legislation.

Justification for the procedure

402. The regulations will be subject to negative procedure. The negative procedure will still provide Parliament the opportunity to debate these matters if necessary, whilst ensuring that changes can be made at speed. This procedure ensures transparency about the decisions made whilst recognising that delegations arrangements may need regular or speedy adjustment.

Clause 60 : Joint working and delegation arrangements – inserting new section 65Z7 into the 2006 Act – power to publish guidance about joint working by relevant bodies
Power conferred on: NHSE
Power exercised by: Statutory Guidance
Parliamentary procedure: None

Context and purpose

403. Section 65Z7(1) provides that NHS England may publish guidance for relevant bodies about the exercise of their powers under section 65Z5 (above) and section 65Z6 (formation of joint committees and pooled funds).

404. Section 65Z7(2) stipulates that a relevant body (see section 65Z5(2)) must have regard to any guidance published under this section.

Justification for taking the power

405. It would not be desirable to write the content of the guidance on information processing into primary legislation. It is likely to include administrative and technical details, and to need updating more frequently than writing it into primary legislation would allow.

Justification for the procedure

406. The requirements in the guidance are likely to be detailed and to be subject to change from time to time depending on the delegation and joint committee arrangements. Given the procedural content of the guidance, a Parliamentary procedure is considered unnecessary.

Clause 61 : References to functions: treatment of delegation arrangements etc. - new section 275A of the 2006 Act – power to create exceptions to the general rule concerning references to "functions"
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

407. Clause 61 inserts a new section 275A into the 2006 Act. It is intended to produce a more consistent approach to the way in which functions are referred to in that Act.

408. The starting point is that a general reference to a person's functions is capable of covering functions delegated to the person, although there may be something about the legislative context to indicate that this is not the intention in relation to a particular reference.

409. The 2006 Act does not take an entirely consistent approach in relation to delegated functions. In some places where a function can be delegated to another, express provision is made to the effect that a reference elsewhere to the recipient's functions includes a reference to the delegated function so far as exercisable by them (see, for example, the current section 13Z4(2) and 14Z24(2)). In other places this is not spelt out. The contrast is potentially unhelpful and new section 275A seeks to address this issue.

410. There are some provisions within the 2006 Act where the starting point explained above would not produce the desired policy result because (for example) a reference to the functions of a body should not, as a matter of policy include a reference to public health functions delegated to it by the Secretary of State under section 7A. To deal with this kind of case, new section 275A(2) confers a power to specify places where a reference to a person's functions do not include delegated functions in regulations.

Justification for taking the power

411. The power provides a mechanism for the Secretary of State to ensure that the general presumption set out a section 275A(1) can be set aside for specific situations. This is necessary because there are limited situations where it is not the policy intention that a reference to a body's function would include a delegated function. It is consider necessary to take a power to set out such exceptions rather than list the exceptions on the face of the Bill because those exceptions may need to be updated from time to time to reflect changing circumstances or different approaches to delegation of functions including to respond to concerns and advice from outside bodies. Taking a regulation-making power provides the necessary flexibility to ensure functions set out in the 2006 Act work in an efficient and transparent way.

Justification for the procedure

412. The power is well defined and limited. Regulations made under this power will not set out any detailed policy. Instead, they will refer to specific delegated functions, which

should not be included in certain references to functions of a body in the 2006 Act. Regulations will provide transparency of this approach. Based on the subject matter of these Regulations and the limited changes they will make, the negative procedure is appropriate.

Collaborative working

Clause 63 : Guidance about joint appointments - inserting new section 13UA into the 2006 Act – power to issue guidance about joint appointments
Power conferred on: NHS England
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

413. A joint appointment will be defined by the Bill as an appointment of a person to a position in—
    - one or more relevant NHS commissioner and one or more relevant NHS provider,
    - one or more relevant NHS body and one or more local authority, or one or more relevant NHS body and one or more combined authority

414. Joint appointments are permissible under existing legislation and there have already been a number of joint appointments at senior executive level, across:
    - ***CCGs and Local Authorities*** – for example, the Chief Executive of Tameside Metropolitan Borough Council is also the Accountable Officer of Tameside and Glossop CCG, one of many such joint appointments, particularly in Greater Manchester;
    - ***CCGs and NHS England*** – for example, the Accountable Officer for the three Surrey Heartlands CCGs is the NHS England Director of Commissioning for Surrey Heartlands; and
    - ***CCGs and providers***[5] – for example, there is now a joint Chief Finance Officer/Director of Finance across Frimley Health FT and Frimley CCG.

415. The Department seeks to encourage joint appointments where they are appropriate and it is envisaged that, in light of the proposals running throughout this Bill for greater working together and integration in the health service, we may see joint appointments being considered and indeed made more often.

416. The joint appointments referred to above were made on the understanding that they are not inconsistent with the statutory powers of NHS bodies. However, matters such as risk of conflicts of interest mean that careful consideration is required before making a joint appointment across different types of organisation, particularly commissioning bodies and providers. Organisations often seek legal advice in relation to proposals for joint appointments, but this can entail significant cost and discourage organisations from pursuing a joint appointment. In some cases, organisations may not take appropriate advice or choose to proceed irrespective of it, resulting in appointments that create a risk of legal challenge because of the extent of the conflicts of interest associated with the joint role.

[5] Providers are the statutory providers, NHS trusts and FTs.

417. The Bill therefore proposes to create a power for NHS England to publish guidance on the use of joint appointments by NHS commissioners and NHS providers.

Justification for taking the power

418. Following feedback from the engagement exercise on the Long Term Plan, the Department understands that many trusts have sought to make joint appointments with CCGs or would welcome the ability to do so. However, there have been issues relating to the lack of clarity about the ability to pursue joint appointments across different organisation types. These issues will become more prevalent as more organisations seek to make joint appointments.

419. By issuing guidance, NHS England will be able to reduce uncertainty over when joint appointments are appropriate. It is intended that this will reduce both the likelihood that an organisation would be inhibited from making a joint appointment if appropriate, or that an organisation would make an inappropriate joint appointment. Organisations will be prompted to consider whether conflicts of interest will arise and whether effective arrangements to manage any conflicts will help mitigate the risk that inappropriate joint appointments are pursued.

420. The level of detail about the circumstances in which joint appointments may be appropriate that it is intended should be covered in the guidance is such that it would not be feasible for it to be dealt with in primary legislation. The guidance will be able to provide practical examples of situations in which joint appointments would be appropriate, in a level of detail that Parliament would not be able to go into. Some organisations take different approaches to the use of job titles and the structure and portfolio of different roles, which would make it difficult to create a definitive list of permitted appointments that applied to all of the organisations in primary legislation.

421. The intention is to issue guidance to encourage joint appointments to be made where it is appropriate and in the interests of each appointing organisation. The guidance will advise that organisations should have a clear rationale for the appointments and provide criteria that the appointing organisations should consider as part of their assessment as to whether the joint appointment should be pursued. It is not the intention to expressly recommend or prohibit any joint appointments in the Bill or to define the types of joint appointment that are permitted.

Justification for the procedure

422. There will be no parliamentary procedure for the publication of the guidance under these provisions. It would be relatively unusual for Parliament to scrutinise statutory guidance of this type. There will, however, be a requirement for consultation by NHS England or such persons as it considers appropriate, prior to the publication (or revision) of the guidance.

Clause 64 : Co-operation by NHS bodies etc.
Amending section 72 and section 82 of the 2006 Act: power to publish guidance in respect of co-operation by NHS bodies etc.
Power conferred on: Secretary of State
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

423. A new guidance making power is to be introduced into sections 72 and 82 of the 2006 Act to allow the Secretary of State to issue guidance on cooperation between NHS bodies, and between NHS bodies and local authorities.

Justification for taking the power

424. New guidance will give organisations greater clarity about what the duties to cooperate mean in practice, which will help build on the innovation, working relationships and positive behaviours that have been seen over the past year, and further embed these behaviours across the health and care system.

Justification for the procedure

425. A Parliamentary procedure is considered unnecessary given the operational nature of this guidance. In addition, the guidance may go into some detail and will need updating from time to time. It would therefore be undesirable to aim to set out its contents in primary legislation.

Clause 65 : Wider effects of decisions: licensing of health care providers, inserting provisions into section 96 of the 2012 Act – power to set or modify licence conditions
Power conferred on: NHS England
Power exercised by: setting or modifying licence conditions
Parliamentary procedure: None

Context and purpose

426. Further to the establishment of the new “Triple Aim” duty, clause65 will enable NHS England, when setting or modifying licence conditions for bodies that provide health care services for the NHS, to set or modify conditions for the purpose of ensuring compliance with the Triple Aim duty.

Justification for taking the power

427. Parliament has already considered it appropriate to delegate the power to set or modify licence conditions on bodies that provide health care services for the NHS, in passing the 2012 Act. (Monitor currently exercises this power, and NHS England, after the merger of Monitor and NHS England will in future exercise it.)

428. This clause does not widen the power substantively; rather it provides that the power may be exercised in such a way that furthers bodies' compliance with a duty that is being proposed in this Bill, which is clearly necessary in light of the creation of this duty.

Justification for the procedure

429. The procedure for setting or modifying licence conditions will remain the same as it presently is, as provided already in the 2012 Act.

NHS payment scheme

Clause 66 and paragraph 3 of Schedule 10 : NHS payment scheme, section 114A – power to publish the NHS payment scheme
Power conferred on: NHS England
Power exercised by: Publishing the NHS payment scheme
Parliamentary procedure: None

Context and purpose

430. Paragraph 3 of Schedule 10 amends Chapter 4 of the 2012 Act which deals with pricing. The amendment changes the name of the national tariff to the NHS payment scheme. The NHS payment scheme will be the document published by NHS England containing rules for determining the price payable for the provision of health care services for the purpose of the NHS. The amendment also widens the scope of the rules contained within the NHS payment scheme document so that it will now include rules which specify prices and rules which specify amounts, formulae or other matters to be used as the basis of which prices are to be determined.

Justification for taking the power

431. As is currently the case with the publication of the National Tariff, the elements of the NHS payment scheme document will require regular updates, for example if NHS England decides to extend the payment scheme to other services or to take into account efficiencies achieved in the provision of services. The need for flexibility to produce new editions of the document make this unsuitable for primary legislation.

Justification for the procedure

432. No Parliamentary procedure is considered necessary, since the NHS payment scheme exists at present as the national tariff, in a non-statutory form, and will be a detailed document, published nationally whose content will change regularly.

Clause 66 and paragraph 3 of Schedule 10 : NHS Payment scheme: further provisions – section 114B – power to direct the commissioner to take steps to stop the breach, to secure that the breach does not continue or recur, or to secure that the position is restored
Power conferred on: NHS England
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

433. Subsections (3) and (4) transfer Monitor's powers of direction in relation to commissioners of health care services for the purposes of the NHS, to NHS England, now that Monitor is abolished. The scope of the power remains in that it was intended to be used where a commissioner either agrees to pay a price which is different from

the price payable under the NHS payment scheme, or the commissioner fails to comply with rules contained in the scheme. As with Monitor before, NHS England may direct the commissioner to take steps to stop the breach, to secure that the breach does not continue or recur, or to secure that the position is restored (as far as reasonably practicable) to what it would have been if the breach had not occurred.

Justification for taking the power

434. Parliament has already deemed it appropriate to delegate this power to Monitor, under section 117(4) and (5) of the 2012 Act. This Bill simply provides that the power is instead exercised by NHS England now that Monitor is abolished and NHS England will take over its functions. This power relates to enforcement action by NHS England: putting the requirements NHS England would set into primary legislation would remove its enforcement role.

Justification for the procedure

435. A Parliamentary procedure is considered inappropriate as this power is about specific enforcement action to be taken by NHS England in relation to specific cases.

Clause 66 and paragraph 3 of Schedule 10 : Objections to proposed pricing method – section 114D – power to make regulations in relation to the proposed pricing method for NHS payment scheme
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

436. Subsection (1)(b) provides for the Secretary of State to prescribe, through regulations, objection percentages for commissioners and for relevant providers of health care services, to the proposed NHS payment scheme. This objection process currently exists for the national tariff.

437. NHS England will be responsible for setting and publishing an NHS payment scheme for NHS services, but before publishing the payment scheme, NHS England must consult with each ICB, each relevant provider and such other persons its considers appropriate. If objections are received by NHS England in that consultation period and those objections exceed the amount prescribed in the regulations, NHS England is to consult with the relevant representative of the ICB and/or relevant provider from whom objections were received.

438. If both the objection percentage of the ICBs and the objection percentage of relevant providers who have objected to the proposed NHS payment scheme, is less than the percentages prescribed by the Secretary of State, then NHS England would be able to proceed and publish the NHS payment scheme.

439. The objection percentage is the proportion of ICBs or relevant providers who are objecting.

Justification for taking the power

440. Delegating the power, as is currently the case with the national tariff, gives the Secretary of State flexibility to adjust the prescribed percentages in the future. This is important as the optimal percentage may change as the commissioner and provider landscape changes. It would therefore be impracticable for Parliament to set this percentage in primary legislation.

Justification for the procedure

441. The use of the affirmative procedure in respect of regulations prescribing the percentages necessary for a reference to be made, is consistent with other regulated industries and is the procedure currently used in respect of the national tariff. The affirmative procedure ensures that Parliament is content with a key aspect of the payment scheme, that is, providing appropriate opportunities for calculating prices and formulae and the resultant prices to challenge those proposals, without creating a provider-led pricing system.

Patient choice and provider selection

Clause 67 : Regulations as to patient choice - amendment of section 6E of the 2006 Act –power to make regulations concerning patient choice
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

442. Clause 67 amends the existing regulation-making power contained in section 6E of the 2006 Act. The amendment requires the Secretary of State to make regulations relating to the exercise of function by NHS England or CCGs, where previously the Secretary of State had discretion as to whether to impose regulations under that section.

443. Additionally, this clause places a duty on the Secretary of State to make provision in such regulations for the arrangements which NHS England and ICBs must make, in the exercise of their commissioning functions, to enable patient to make choices related to specified treatments and other services. These specified treatments and other services are those which the Secretary of State considers it appropriate to do so, and specifies in the regulations.

444. The clause also provides a power (rather than a duty) for the Secretary of State to make other provision to ensure that NHS England and ICBs, in the exercise of their commissioning functions, promote and protect the rights of patients to make choices.

445. The intention of this delegated power is to ensure that robust provisions may be put in place which retain flexibility in the context of a changing range and development of health treatments and services.

Justification for taking the power

446. Parliament has already deemed it appropriate to delegate a regulation-making power in relation to patient choice to the Secretary of State, under section 75(1)(b) of the 2012 Act, which this provision replaces. This Bill provides that the power is instead framed as a duty (so as to strengthen the protections for patient choice).

447. The Secretary of State would wish to retain flexibility in relation to other provisions which may be necessary in the interests of securing patients' rights to make choices, and in relation to which treatments or other services are considered appropriate. The treatments and services it is appropriate to cover with these provisions may change over time.

Justification for the procedure

448. The power would concern what arrangements NHS England and ICBs must make to protect and promote patient rights in relation to choice. These arrangements will

necessarily need to be flexible over time to allow for technological developments and appropriate operational practices.

449. The negative procedure enables the legislation to be more easily adjusted to respond to differing or changing circumstances.

Clause 67 : Regulations as to patient choice – inserting section 6F to the 2006 Act – power to make directions to ensure proper enforcement of regulations relating to patient choice requirements
Power conferred on: NHS England
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

450. The direction-making powers relate to ensuring proper enforcement of the regulations relating to patient choice requirements described above. These do not relate to any criminal sanctions. Rather, they give NHS England the power to direct and ICB to put in place measures to prevent failures to comply with the requirements which the Secretary of State has set out in the regulations, or to remedy a failure to comply with such (following an investigation).

Justification for taking the power

451. This is an administrative and operational function. NHS England does not have power to set the requirements under these powers; instead it is to ensure compliance and remedy failure to comply with the regulations as made by the Secretary of State. NHS England will be best placed to ensure this enforcement and are also given powers of investigation which would allow them to monitor ICBs' compliance.

Justification for the procedure

452. Directions given by NHS England to ICBs relate to increasing adherence to the regulations described above relating to patient choice requirements. Given the administrative and operational nature of the directions, Parliamentary scrutiny is considered unnecessary. Most directions are given in writing and are not subject to any Parliamentary procedure. A Parliamentary procedure is considered inappropriate as this power is about specific enforcement action to be taken by NHS England in relation to specific cases.

Clause 67 : Regulations as to patient choice – inserting section 6G to the 2006 Act – power to issue guidance on the exercise of patient choice powers
Power conferred on: NHS England
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

453. These provisions insert into the 2006 Act a guidance-making duty which requires NHS England to publish guidance on how it intends to exercise the patient choice powers conferred on it by the Bill and regulations made under the patient choice provisions. The duty will apply to NHS England as soon as the patient choice provisions come into force.

454. In order that the Secretary of State can maintain proper oversight of and control over the guidance produced by NHS England, the Secretary of State's approval must be obtained before the guidance may be published.

Justification for taking the power

455. New guidance will give ICBs clarity on what to expect from NHS England in relation to the enforcement of patient choice, and so the expectations placed on the ICBs themselves. This will help support the patient choice rights, and embed processes which support these in the wider health and care system.

456. The guidance is intended to cover detail as to the practical approach NHS England will take to the performance of its functions in relation to patient choice, including NHS England's exercise of its investigatory functions, and the expectations on an ICB in such a situation. This is a level of detail which cannot reasonably be provided in primary legislation. The body which will be best placed to provide this guidance is NHS England itself.

Justification for the procedure

457. There will be no parliamentary procedure for the publication of guidance. It would be unusual for there to be parliamentary scrutiny of this type of statutory guidance.

458. As a primary safeguard, NHSE England must obtain the Secretary of State's approval of the guidance before it may be published; this will allow the department to ensure additional oversight.

Clause 68: Procurement regulations - inserting new section 12ZB into the 2006 Act – power for the Secretary of State, by regulations, to impose requirements on relevant authorities in relation to the procurement of health care services for the purposes of the health service, and for NHS England to publish guidance on compliance with these regulations
Power conferred on: Secretary of State (regulation); and NHS England (guidance)
Power exercised by: Regulations; guidance
Parliamentary procedure: Negative for regulations, none for NHSE guidance

Context and purpose

459. Clause 67 inserts section 12ZB into the 2006 Act, which contains a power enabling the Secretary of State to make regulations imposing requirements on relevant authorities in relation to the procurement of health care services for the purposes of the health service

in England (new section 12ZB(1)(a)). The relevant authorities that this regime will apply to are combined authorities, ICBs, local authorities in England, NHS England, NHS foundation trusts and NHS trusts. “Health care services” are defined as in Part 3 of the 2012 Act (new section 12ZB(7)).

460. The purpose of the power is to allow for the procurement of health care services by these listed bodies to be brought outside of currently applicable procurement rules, and for a new system of procurement rules to be put in place which will aim to reduce bureaucracy on commissioners and providers of health care services, and reduce the need for competitive tendering where it adds limited or no value. The intention is that, via the regime to be introduced in regulations, commissioners of NHS and public health care services will be encouraged to act in the best interests of patients, taxpayers, and the local population when making decisions about arranging healthcare services.

461. The clause also allows for regulations to make provision in relation to mixed procurements of health care services and other services or goods (new section 12ZB(1)(b)). The regulations may include provision in relation to the general objectives of procurement and procurement processes (new section 12ZB(2)) and may make provision for the purposes of ensuring transparency or fairness, verifying compliance with the regime and managing conflicts of interest (new section 12ZB(3)).

462. The clause also allows NHS England to publish guidance about compliance with the requirements imposed by the regulations (new section 12ZB(5)). Before publishing this guidance, NHS England must obtain the approval of the Secretary of State (new section 12ZB(6)).

<u>Justification for taking the power</u>

463. The delegated power to make regulations inserted by section 67 is considered appropriate for the following reasons:

a. Consultation and development of the regime:

i. Initial consultation has been carried out on the content of the regime by NHS England, but it has not yet been possible to fully analyse the results of that consultation and to follow up with the sector on a more developed proposal. Putting the detailed provisions in relation to the new procurement framework in regulations, and consulting on those regulations, will ensure that the views of the sector can be properly integrated into the regulations and the new procurement regime.

ii. Additionally, we expect that a Cabinet Office procurement Bill will most likely follow this Bill through passage, which may alter existing legal procurement frameworks. Retaining flexibility in the implementation of this regime will also allow any changes to procurement law introduced by that Bill to be taken account of.

b. Need for flexibility:

i. Outlining the regime in regulations rather than in primary legislation allows for flexibility in the regime in the future. In particular it is intended that the regulations will set out key criteria that commissioners should take into account when selecting a provider to provide health care services. As the nature of the health service and the challenges that it is facing may change over time, it may be appropriate to alter those criteria as time goes on so that they are more appropriate for the health service at that point in time. This is easier to achieve where the regime is set out in regulations.

464. The power for NHS England to publish guidance is considered appropriate as NHS England has oversight of most of the commissioners and providers within the health care system, and so is best placed to provide guidance to the relevant authorities on how they meet their obligations under the new procurement regime. It is however recognised that NHS England is itself captured by the regime. This is partly why Secretary of State approval is required prior to the publication of such guidance – to ensure that any guidance issued is appropriate for all the commissioners to which it applies.

Justification for the procedure

465. As an insertion into the 2006 Act, the regulation-making power is subject to the procedure generally applicable to regulations made under that Act, which is the negative procedure (see section 272(4) of that Act). The Department thinks that the negative procedure is suitable for these regulations in line with the majority of the other regulation-making powers in that Act as it continues to ensure transparency but also provides flexibility to amend the regulations speedily if necessary.

466. Section 272(8) of the 2006 Act would allow this power to be used to make incidental, supplementary, consequential, saving or transitional provisions, including amending, repealing or revoking enactments. Therefore the regulation-making power could technically be used to amend primary legislation. However, the only current intended consequential amendments would be to secondary (the Public Contracts Regulations 2015) and it is thought that any amendments to primary would be very minor, making the negative procedure still sufficient.

467. As noted above however, we expect that a Cabinet Office procurement Bill will most likely follow this Bill through passage. It is possible that the interaction between that Bill and this one may require some amendments to be made to the procurement regulation-making power in this Bill, which could include a reconsideration of the applicable procedure.

Miscellaneous

Clause 75 : Tidying up etc provisions about accounts of certain NHS bodies – inserting a new section 29A and paragraph 11A in Schedule 4 to the 2006 Act – power to make directions relating to accounts of certain NHS bodies
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

468. Schedule 15 to the 2006 Act needed revisiting in light of old amendments to that schedule and additional ones that arose out of the merger. The decision was taken to abolish that Schedule and carry over provisions relating specifically to NHS trusts and Special Health Authorities, as they were the only bodies remaining to which Schedule 15 applied.

469. Schedule 15 contained direction making powers which allowed the Secretary of State to give directions to a SpHA and an NHS trust as to the form in which its accounts must be kept. That power has been carried over into new section 29A(4) in relation to Special Health Authorities, and new paragraph 11A of schedule 4 in relation to NHS trusts.

Justification for taking the power

470. It is important for SpHA and NHS trusts to maintain accounts in an appropriate format. The form might need to change over time so a power of direction is considered the most appropriate power to achieve this flexibility.

Justification for the procedure

471. The direction making power already exists and is not subject to the Parliamentary procedure. The Parliamentary procedure is not considered necessary given that accounting requirements for public bodies are technical matters and it is standard practice to use directions for this purpose.

Clause 76: Repeal of spent powers to make transfer schemes
Power conferred on: Secretary of State
Power exercised by: Scheme
Parliamentary procedure: None

Context and purpose

472. This clause repeals the spent powers in section 300 and 301 of the 2012 Act and substitutes a new version of section 302. Sections 300 and 301 were powers that allowed the Secretary of State to make schemes for the transfer of staff and property from one body to another, in connection with the establishment or abolition of a body under that Act. Section 302 is a power that allows a further transfer scheme in relation

to any property, rights or liabilities that have been transferred under a scheme under section 300(1) from a Primary Care Trust, Strategic Health Authority or the Secretary of State to a Special Health Authority or a qualifying company. The section 302 power is still in use, for example to transfer properties from NHS Property Services (a qualifying company) to NHS trusts or NHS foundation trusts where it is more appropriate for the trusts to manage their own estates.

473. The policy intention is to recreate section 302 to continue to enable those transfers to be made, and to update the list of possible bodies a transfer scheme can transfer a property too, as the existing list in Schedule 22 of the 2012 Act contains references to bodies that have since been abolished, or are no longer considered appropriate to be transferors under such a scheme.

Justification for taking the power

474. The details of how transfer schemes will operate is technical and would require more detailed consideration of the property to be transferred that could be appropriately included in primary legislation. It is also the case that the details of which properties will be transferred to which bodies will need to be determined on a case by case basis as the need arises.

Justification for the procedure

475. Any transfer scheme made under this provision is likely to include more technical detail than is normally included on the face of a Bill. The Department do not consider that it is necessary to subject the resulting transfer schemes to a Parliamentary procedure, as reviewing the specific details set out in an individual transfer scheme would not be a good use of Parliamentary time.

PART 2

Information standards

Clause 79 : Information standards. Power for regulations to confer on a person who publishes an information standard the power to waiver a person's requirement to comply with that information standard; power for regulations to provide for requirements and procedures in relation to waivers; duty to make regulations about the procedure to be followed in connection with the preparation and publication of information standards; power to make regulations requiring an information standard to be reviewed periodically.
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

476. Sections 250 and 251 of the 2012 Act provide for the preparation and publication of information standards by the Secretary of State (in relation to health services and adult social care) and NHS England (in relation to NHS services only). Information standards set standards in relation to the processing of information.

477. The legislation currently imposes a duty to have regard to information standards on the Secretary of State; NHS England (formerly the National Health Service Commissioning Board), public bodies which exercise functions in connection with the provision of health services or adult social care; and persons providing such services or care pursuant to arrangements with a public body.

478. Clause 79 would extend section 250 to all regulated providers of health services or adult social care regardless of whether they are providing those services or care pursuant to arrangements made with a public body. It would also replace a person's duty to have regard to information standards with a duty to comply with information standards that apply to them, except that the Secretary of State would have a duty to have regard to an information standard published by NHS England that applies to the Secretary of State.

479. Clause 79 would also provide powers for regulations to confer on a person who publishes an information standard a power to waive the requirement to comply with that information standard (new subsection (6B) of section 250) and to include provision relating to requirements and procedures in connection with waivers (new subsection 6C or section 250). It would require regulations to make provision about the procedure to be followed in connection with the preparation and publication of information standards and enable regulations to require an information standard to be reviewed periodically (substituted section 251).

Justification for taking the power

480. The power to waive a requirement to comply with an information standard involves matters of administrative and procedural detail which are more suitable for secondary legislation, such as the circumstances in which waivers may be granted, procedures in connection with waivers and requirements for specified information about waivers to be included in information standards. Flexibility is required so that the requirements and procedures relating to waivers may be varied to reflect the differing subject matter of information standards and the potential need to respond to changing situations.

481. The procedure to be followed in connection with the preparation and publication of information standards is also considered to be a matter which is more appropriate for secondary legislation, because it may need to vary according to the nature of the information standard (for example by reference to whether a standard is being newly published or being revised) and to reflect the fact that the procedures may need to be updated from time to time. Requirements for periodic review are also likely to vary depending on the nature of the information standard. By way of example, more frequent review is likely to be needed for a standard that relates to a fast moving medical field. In addition, clause 79 would impose a constraint on the regulation making power by requiring the Secretary of State, before laying the regulations, to consult such persons as the Secretary of State considers appropriate. This is an added safeguard.

Justification for the procedure

482. Although the regulations would deal principally with administrative procedures, those procedures are the main mechanism for the scrutiny and review of information standards, as well as potentially relating to a waiver of the requirement to comply with information standards. As such, they are an important safeguard for the providers of health services and adult social care that will be bound by information standards and, in the case of private providers, who could be subject to financial penalties for non-compliance. The affirmative procedure will ensure Parliament is able to subject these procedures to detailed scrutiny.

Sharing anonymous information for health and social care purposes

Clause 80 : Sharing anonymous health and social care information. Power for Secretary of State to make regulations to create exceptions to the power for public bodies exercising health or adult social care functions to require information from each other or from private providers
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

483. New section 251D introduced by clause 80 introduces a power for public bodies which exercise relevant health or adult social care functions to require other such bodies, or private persons providing health services or adult social care pursuant to arrangements made with such a public body, to provide information. The power applies only to information that is not personal information (that is, information which is in a form that does not identify any individual or enable the identity of any individual to be ascertained, i.e. anonymous information); and that relates to the activities of the body or person in connection with the provision of health services or adult social care in England, and, in the case of private persons, in pursuance of arrangements made with a public body.

484. Regulations under section 251D would enable the introduction of exceptions to the requirement to comply with such a request. Exceptions may be framed by reference to certain bodies or descriptions of bodies, descriptions of information, or otherwise.

Justification for taking the power

485. The provisions are just one element of a range of proposals and the wider draft data strategy, the aim of which is to enable the safe sharing of data in support of individual care, population health and the effective functioning of the health and care system. They are linked to the provisions strengthening the duty to cooperate across the health and care system, including ICBs), requiring them to have regard to the effects of their decisions on the health and well-being of the people of England; the quality of services and the efficiency and sustainability in relation to the use of resources (see section 14Z43 of the 2006 Act clause 93).

486. The Department has published a draft data strategy for health and care to highlight the importance of and enable the safe sharing of data in support of individual care, population health and the effective operation of the health and adult social care system. The data strategy was published in draft form on 22nd June 2021, to allow for engagement with a wide range of stakeholders before it is finalised.

487. The Department has carefully considered the need to be able to monitor and assess the effectiveness of the various proposals being implemented, to enable the draft data strategy to be finalised with stakeholder engagement, and to respond flexibly and swiftly if it becomes evident that it is appropriate to introduce exceptions to the scope of the

power to require provision of anonymous data to ensure the policy aims are achieved and that any additional burden on health and social care bodies is minimised.

Justification for the procedure

488. The Department considers that regulations made under subsection (3) should be subject to the negative procedure. This procedure enables legislation to be easily adjusted to respond to differing or changing circumstances. The regulations may only make exceptions to the power of a public body to require anonymous information to be provided and, therefore, are unlikely to contain policy issues that require in depth Parliamentary debate and consideration.

Collection of information about adult social care

Clause 83 : Collection of information about adult social care - Power for Secretary of State to direct the Health and Social Care Information Centre or a Special Health Authority about the exercise of those functions
New section 277C
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

489. New section 277C inserted into the 2012 Act by clause 83 enables the Secretary of State to direct the Health and Social Care Information Centre, or a SpHA performing functions in respect of England, to exercise the Secretary of State's functions under new section 277A (also inserted by clause 83). It also enables the Secretary of State to give directions about the exercise of those functions. Section 277A enables the Secretary of State to require regulated providers of adult social care to provide information relating to themselves, their activities in connection with the provision of adult social care or persons to whom they have provided such care.

Justification for taking the power

490. The Secretary of State would wish to retain operational flexibility in the exercise of the functions in question, and to retain the discretion to delegate, or to not delegate, them to either the Information Centre or a SpHA, to delegate only parts of the functions and to revoke a decision to delegate them. The power to direct these bodies about the exercise of the functions in question is necessary in order to cover details such as how the functions are to be exercised including specific information to be required to be provided, the frequency provision and the form in which information is to be provided, which may be different for different organisations or subject to change (for instance to support rapid response to pandemics). Thus, the directions would contain matters of detail in relation to which the flexibility to make amendments would be important so that they can be kept up to date. This would provide flexibility to cater to changing circumstances. Delegated legislation is therefore considered appropriate to provide for the necessary level of detail and in order to allow the flexibility to amend where necessary. The power to delegate thus allows for flexibility in relation to the performance of the functions.

Justification for the procedure

491. The power would concern the question of whether an existing function should be exercised by specified statutory bodies rather than the substance of the functions. Given the administrative and operational nature of the directions, Parliamentary scrutiny is considered unnecessary. Under section 304 of the 2012 Act the directions would be required to be given in writing.

New section 277D - Power for Secretary of State to make arrangements for a person to exercise the Secretary of State's functions under section 277A; power to make regulations to prescribe the person with whom such arrangements may be made
Power conferred on: Secretary of State
Power exercised by: Regulations and arrangements
Parliamentary procedure: Negative (in relation to Regulations)

Context and purpose

492. New section 277D inserted into the 2012 Act by clause 83 enables the Secretary of State to make arrangements for a person prescribed by regulations to exercise the functions of the Secretary of State under section 277A. Section 277A enables the Secretary of State to require regulated providers of adult social care to provide information relating to themselves, their activities in connection with the provision of adult social care or persons to whom they have provided such care. The power to make arrangements would be capable of being exercised in a manner similar to directions under the 2012 Act, for example by enabling arrangements to be made for functions to be exercised wholly or to a limited extent and in specific cases or circumstances or more generally.

Justification for taking the power

493. Where, under section 277D, the power to delegate functions under section 277A is exercised, the Secretary of State would wish to retain operational flexibility in relation to the nature and extent of the arrangements and as to the identity of the person with whom those arrangements are to be made as these may fluctuate over time. The functions themselves and the restrictions on the exercise of those functions would be set out on the face of the Bill, namely in sections 277A and 277B respectively.

Justification for the procedure

494. The regulations would relate to the identity of the person to whom the Secretary of State's functions under section 277A are to be delegated. This may fluctuate over time. Given the administrative and operational nature of the arrangements, Parliamentary scrutiny is considered unnecessary.

Clause 84 : Enforcement of duties against private providers - Power to make regulations to confer powers on the Secretary of State to impose a financial penalty on persons who fail to comply with information standards or information requirements or who provide false or misleading information; requirements and powers for the regulations to include certain provisions
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

495. New section 277E inserted by clause 84 provides for regulations to confer powers on the Secretary of State to impose a financial penalty on persons other than public bodies who, without reasonable excuse:
    - fail to comply with an information standard (unless that requirement has been waived);
    - fail to comply with a requirement to provide information imposed under:
        - new section 251ZA(1) inserted by clause 79 (provision of information to the Secretary of State for monitoring compliance with information standards);
        - new section 251D(1) inserted by clause 80 (sharing of anonymous information for health or social care purposes);
        - section 259(1)(aa) inserted by clause 82 or section 259(1)(a) (the Health and Social Care Information Centre's power to require information for the purposes of its functions); or
        - new section 277A(1) inserted by clause 83 (provision of information by regulated providers of adult social care to the Secretary of State);
    - provide, in response to any of the above requirements, information that is false or misleading to a material extent.

496. Clause 84 provides that the amount of the financial penalty is to be specified in, or determined in accordance with, the regulations. Clause 84 requires the regulations to include various provisions such as provision requiring the Secretary of State to give a person written notice of the proposed financial penalty before imposing it, provision ensuring that the person is given an opportunity to make representations, and provision enabling a person to appeal to the First-tier Tribunal.

497. The purpose of this clause is to provide a mechanism to enforce the duty to comply with information standards and requirements to provide information.

It is intended that penalties will be a last resort and it is not expected that very many penalties will need to be imposed.

Justification for taking the power

498. The substance of the duties which could be subject to the civil penalty regime would be set out in the primary legislation. It is considered appropriate for the amount of the penalty and the details of the procedure by which the financial penalty regime is to be administered to be set out in regulations. This is to avoid excessive detail in the primary legislation and to allow for appropriate regimes to be devised for different requirements that take into account the varying nature of the duties to be enforced.

499. Setting out the amount of the financial penalty in regulations allows flexibility for this to be varied according to the provisions in relation to which the penalty applies and their relative seriousness, which may vary over time.

500. Further, clause 84 sets out details of provisions which the regulations must or may include and this sets safeguards and constraints. Examples of provision which must be included are provision ensuring a person is given an opportunity to make

representations and provision enabling a person to appeal to the First-tier Tribunal. Examples of provision which may be included are provision enabling notices to be withdrawn, or requiring the withdrawal of a final notice, and provision for the financial penalty to be increased in the event of late payment.

501. The above approach is consistent with the existing approach to similar civil penalty regimes in legislation.

Justification for the procedure

502. The affirmative procedure will provide Parliament with the opportunity to scrutinise and debate the implementation and proportionality of the civil penalty regime and it is considered that this provides the appropriate level of scrutiny.

Clause 84 : Enforcement of duties against private providers
Power for Secretary of State to direct a Special Health Authority to exercise the functions of the Secretary of the State under regulations under section 277E which concern enforcement of information requirements
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

503. New section 277F inserted by clause 84 enables the Secretary of State to direct a SpHA to exercise the functions of the Secretary of the State under regulations made under section 277E (enforcement), and to give directions about the exercise of those functions, including directions as to the processing of information that the SpHA obtains by exercising the functions.

Justification for taking the power

504. The Secretary of State would wish to retain operational flexibility in the exercise of the enforcement functions in question, and to retain the discretion to delegate, or to not delegate, them to a SpHA, to revoke a decision to delegate them and to ensure that the most appropriate SpHA is able to exercise those functions in relation to the respective requirements. SpHA are already vehicles for the exercise of the functions of the Secretary of State and others via directions under section 7 of the 20016 Act. The power to direct a SpHA about the exercise of the functions in question is necessary in order to cover matters such as how the functions are to be exercised. Thus, the directions would contain matters of detail in relation to which the flexibility to make amendments would be important so that they can be kept up to date. This would provide flexibility to cater to changing circumstances. The power to delegate enforcement functions to a SpHA thus allows for flexibility in relation to the performance of those functions.

Justification for the procedure

505. The power would concern the question of whether an existing function should be exercised by a SpHA rather than the substance of the functions. Given the administrative and operational nature of the directions, Parliamentary scrutiny is considered unnecessary. The regulations containing the enforcement functions would themselves have been subject to Parliamentary scrutiny in accordance with the affirmative procedure, and the SpHA would be bound by the requirements in those regulations. Under section 304 of the 2012 Act the directions would be required to be given in writing.

Medicine information systems

Clause 85 : Medicine information systems
Power conferred on: Secretary of State and the Department of Health in Northern Ireland
Power exercised by: Regulations. Regulations may confer a direction making power.
Parliamentary procedure: Affirmative

Context and purpose

Policy purpose

506. The purpose of these new sections is to enable NHS Digital to collect information on the use of medicines (via secondary legislation that places obligations about the provision of information) on a UK-wide basis, including information from within devolved administrations and private healthcare providers. The principal power may only be exercised for the specified purposes set out in section 7A(1). They are purposes relating to the safety, quality and efficacy of human medicines and the improvement of clinical decision-making in relation to human medicines. The policy intention is that information in the medicines information system(s) (MIS) will then be provided to the MHRA who will use it to develop registries on the use of medicines in the UK.

507. The establishment of registries was recommended in the Report of the Independent Medicines and Medical Devices Safety Review (published July 2020). Registries established using information from the medicines information system(s) would be used to provide regulators with high quality evidence regarding the use, benefits and risks of medicines which will to inform regulatory decision-making.

508. Because the intention is to collect information from all UK nations, it is necessary to confer UK-wide functions on NHS Digital. Clause 85 therefore seeks to insert the necessary provisions into the MMD Act which has UK-wide extent. It is also considered appropriate to include the provisions in this Act so the provisions for medical device and medicines information systems are in the same legislation.

509. Clause 85 amends Part 2 of the MMD Act 2021 by introducing two new sections: 7A (information systems) and 7B (offence of disclosing information). It also amends sections 19 (Information systems) and 43 (Power to make consequential etc. provision) of the MMD Act and makes consequential amendments to other sections of that Act, that relate to reporting requirements (section 46) and the applicable parliamentary procedure (sections 44 and 47). Finally, 85 also makes a consequential amendment to section 253 of the 2012 Act.

Section 7A

510. Section 7A introduces a delegated power to establish and operate one or more medicines information systems. The power specifies that the Health and Social Care

Information Centre (a body established under section 252 of the 2012 Act and known as NHS Digital) will establish and operate the system(s). It is closely based on section 19 of the MMD Act, which provides for the establishment and operation of one or more medical device information systems.

511. On the matter of who may exercise the power, section 7A respects the Northern Ireland devolution settlement in relation to the devolved field of human medicines. The delegated power in section 7A would be exercisable in the following way:
    a. In relation to GB - the Secretary of State only;
    b. In relation to NI – either (a) just the Department of Health in Northern Ireland or (b) the Department of Health in Northern Ireland and Secretary of State acting jointly.

512. The effect being that in relation to UK-wide regulations, the Department of Health in Northern Ireland and the Secretary of State would act in cooperation so as to exercise their powers in the same instrument. This follows the approach taken in section 2 of the MMD Act.

513. As mentioned above, regulations made under section 7A *may* confer a direction-making power. To reflect the devolution position, the clause provides for this power to be exercised by the Appropriate Authority, in the same way as the principal delegated power.

Section 7B

514. Section 7B makes it an offence for a person to use or disclose information received pursuant to regulations made under to section 7A in contravention of these regulations. This section is closely based on sections 40(2) to (4) of the MMD Act, which introduces a similar offence for information relating to medical devices.

Amendments to section 19 of the MMD Act

515. Section 19 of the MMD Act 2021 provides a delegated power to establish and operate medical device information systems (MDIS). Clause 85 would make amendments to this section. The proposed amendments to section 19 relate to provision that can be made in regulations about the disclosure of information in relation to MDIS. The first of these will ensure regulations can make provision for the disclosure and publication of not only the data contained in the information system but also the information it has been combined with for analysis. The second amendment to section 19 will make it explicit that provision can be made in regulations that a disclosure of information under the regulations does not breach an obligation of confidence or other restriction on disclosure (other than a restriction under data protection legislation). These amendments ensure there is consistency with the new section 7A in those two areas, thereby addressing any potential uncertainty about the interpretation of this section which may be created by the introduction of the new section 7A.

Amendments to section 43 of the MMD Act

516. Like section 19 of the MMD Act, the new powers in section 7A will extend to the whole of the UK, whereas the general functions of NHS Digital in the 2012 Act are limited to England and Wales.

517. There may be a need to make further consequential amendments to Chapter 2 of Part 9 of the 2012 Act to ensure NHS Digital can carry out its UK-wide MIS and MDIS functions. Clause 85 amends section 43 of the MMD Act to enable consequential provision made in regulations under section 7A or 19, to include provision amending or modifying the wording of certain provisions or amending their territorial extent so they apply UK-wide.

Amendments to sections 44, 46 and 47 of the MMD Act

518. These amendments ensure the regulations made under section 7A are subject to the appropriate reporting requirements and parliamentary procedure.

Justification for taking the power

519. The delegated power in section 7A is considered appropriate for four main reasons:

a) Consultation

520. The intention is that any MIS and subsequent registry that is established by the MHRA is established on the basis of close collaboration between MHRA and stakeholders. It will be a legal requirement to consult under section 45 MMDA. The information system will be used by MHRA as a critical tool to inform regulatory decision making, and the data held will also be capable of supporting other stakeholders in the healthcare system, for example to ensure both healthcare providers and patients have the information they need to make decisions about their care.

521. Putting the detailed provisions regarding how the information system will operate in regulations and making those regulations subject to public consultation will ensure that the voices of patients, clinicians, and other healthcare providers are heard before the regulations are made and the information systems are established. It will also enable the Government to use these insights into stakeholders' needs and challenges to ensure medicines information systems are able to serve the intended purpose as a central tool for improved patient safety. It is therefore integral to the proper functioning of the MIS that the detail on how the system will operate is set out in regulations and first consulted on with all stakeholders to ensure the most effective system is put in place.

b) Need for flexibility

522. It is important that the legislative framework for medicine information systems can be amended quickly to enable the collection of the information required to operate effective medicines registries.

523. Where a new medicine is introduced to the market or new safety concerns about an existing medicine are identified and it is necessary to initiate a new medicine registry, new types of information may need to be collected from new sources and in novel ways.

524. Similarly, if new concerns or issues are raised about a medicines which is already the subject of an information system, the data collected about the use of that medicine may need to be extended or amended as it will not always be possible to predict what issues may arise when an information system is established.

525. The kinds of medicines coming onto the market are constantly evolving (e.g. personalised medicines) and it is not possible to predict the types of data which may be needed to establish future information systems, nor the potential sources of this information. Further, the ways in which data is captured across the healthcare system also changes regularly. Flexibility is therefore necessary to ensure information systems are appropriate for emerging treatments and reflect new information gathering practices.

526. To respond to this need for flexibility, sections 7A(5)(d) and 7A(7) enable the regulations made under section 7A(1) to provide that the Appropriate Authority may use directions to specify what information NHS Digital is to collect. The intention behind this provision is to allow the Appropriate Authority to amend what information is collected by NHS Digital and respond to emerging health concerns efficiently.

527. However, it may also be necessary to amend other provisions in the legislative framework. For example to provide for the collection of information from new sources and or to set out new mechanisms for collecting this information. It is therefore considered appropriate that the legislative framework for medicines information systems is contained in regulations. This use of secondary legislation seeks to ensure the framework for MIS stays up to date and allows the Secretary of State to respond to emerging health concerns in a timely manner.

c) Consistency with existing legislative framework

528. Clause 85 is closely based on the provisions for MIDS in section 19 of the MMD Act. These provisions also give a delegated power to the Secretary of State. Given the similarities between the two systems, it is appropriate that the powers for medicines and MIDS are consistent where possible.

d) Appropriate limitations

529. Clause 85 includes a number of provisions restricting how the power in section 7A can be exercised Section 7A(1) provides that the Secretary of State can only exercise the power to make provisions about the establishment and operation of the MIS for purposes relating to:
    a. the safety, quality and efficacy of human medicines; and
    b. the improvement of clinical decision-making in relation to human medicines.

530. The Department considers that these limitations deliberately narrow the scope of the power to only what is necessary for the effective operation of the MIS.

531. The remaining subsections of section 7A provide detail on what provisions can be included in the regulations. Section 7A(2) sets out the categories of provisions that may be included in the regulations. Including provision—

    a. about the information in relation to human medicines which may or must be entered or retained in an information system established under subsection (1);
    b. requiring information to be provided to the Information Centre for the purposes of its functions under the regulations;
    c. about the use or disclosure of information contained in an information system established under subsection (1);
    d. requiring the Information Centre to have regard to specified matters in exercising its functions under the regulations.

532. Sections 7A(3) – (8) set out more granular detail about what provisions can be included. These provisions are not exclusive to provide some element of flexibility (the need for which is explained above). However, the specificity of the lists means there is limited scope for including provisions which do not fall within the types of provisions listed.

The amendment to section 19 of the MMD Act

533. The amendment to section 19(6) ensures that data analysed in combination with data in the information system can be disclosed and published. Section 19(6)(a) already provides that regulations can make provision about the analysis of information contained in the information system in combination with other information. To ensure that the benefits of that analysis can be reaped, these amendments will make it clear that the regulations can also make provision about the subsequent publication and disclosure of that combined information.

534. The addition of section 19(7A) makes it clear that regulations can provide for a disclosure of confidential information, such as patient information, that would otherwise be a breach of confidence. It will be important that patient information can be disclosed to, and in some circumstances by, NHS Digital in order to ensure that the information system can fulfil the purposes for which it was established. The purposes for which an information system may be established are set out in section 19(1) and include purposes relating to the safety and performance of medical devices and the safety of the individuals that are treated with them.

535. The power to amend Chapter 2 of Part 9 of the 2012 Act is considered appropriate for three main reasons:

    a. *Dependency on exercise of principle delegated power*
        i. Whether there is a need to amend the provisions of Chapter 2 of Part 9 of the 2012 Act and what amendments are required will depend on how the principal regulation-making power is exercised. It is, therefore, considered appropriate for any amendments to the 2012 Act to be made at the same time the principal power is exercised.

b. *Location of amendments*

i. It is considered clearer for consequential amendments to form part of the larger scheme of which they are a part. The Department therefore considers it appropriate for any amendments to the 2012 Act to be set out in the regulations which will provide the legislative framework for the medicines and MIDS(s). This is reflected in the drafting of the amendment to section 43 which provides that the amendments to the relevant chapter of the 2012 Act are to be made in the regulations made pursuant to sections 7A and 19.

c. Appropriate limitations

i. The power to amend the 2012 Act provisions is not intended to be used to make significant changes to the 2012 Act. To reflect this intention, the power to amend the Act has been limited to the making of '*consequential, supplementary, incidental, transitional, transitory or saving provision*' and the more material change to section 253 has been made in the Bill itself. The Department considers that the scope of the power is therefore suitably limited.

Justification for the procedure

536. Clause 85 provides that regulations made in exercise of the power in section 7A(1) will be subject to the affirmative procedure (see clause 85 which amends section 47 of the MMD Act).

537. The Department has considered whether the negative procedure would be appropriate. However, given that the regulations made under section 7A will place obligations to provide information to NHS Digital on a number of people/bodies and are likely to require the collection of personal information, the Department considers that it is appropriate to apply the enhanced level of scrutiny to regulations possible under the affirmative procedure. This procedure is also considered appropriate for regulations that amend or modify primary legislation (see clause j901(5)(b)).

538. Further, the MMD Act requires the affirmative procedure to be used for the making of regulations relating to the establishment of MIDS under section 19 and the for the making of the majority of other regulations relating to the regulation of human medicines made under MMD Act powers. It is therefore considered appropriate for the same approach to be taken to regulations made under new section 7A.

PART 3

Secretary of State's powers to transfer or delegate functions

Clause 87: power to transfer functions between bodies
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

539. This clause creates a new power for the Secretary of State to make regulations providing for the transfer of functions between "relevant bodies". The "relevant bodies" are the following NDPBs:

a) **NHS England**
b) **Health Education England**
c) **The Health and Social Care Information Centre (operationally known as "NHS Digital")**
d) **The Health Research Authority**
e) **The Human Tissue Authority**, and
f) **The Human Fertilisation and Embryology Authority**.

540. The regulations made under the powers may repeal, revoke or amend provision made by or under an Act (sub-section (5)) – so they are "Henry VIII" powers.

541. The power will only be exercisable when the Secretary of State considers that it would serve the purpose of improving the exercise of public functions, having regard to efficiency, effectiveness, economy and securing appropriate accountability to Ministers. (sub-section (2))

542. The Bill will make provision that the Secretary of State must consult any body to whom proposed regulations relate, in certain circumstances the devolved authorities, and such other persons as the Secretary of State considers appropriate.

Justification for taking the power

543. The power is a Henry VIII regulation making power. This is necessary because the relevant ALBs are currently established in primary legislation and so it may be necessary to make changes to those provisions when functions are transferred. The power is contained in certain ways - in particular, due to the limited number of ALBs it applies to, the test which must be fulfilled before the power can be exercised, the consultation provisions included and the regulations being subject to the affirmative procedure.

Policy imperative for increased flexibility:

544. The purpose of the power is to give the Secretary of State the ability to make changes in a timely fashion to the ever evolving and unpredictable challenges that the health service will face in the future. The current process for making changes to improve the ALB landscape is unsatisfactory in a system where the NHS is ever changing: the current balance of powers prohibits the Department from responding to or pre-empting these changes. The Department have sought to ensure that the power goes no further than is necessary and there are safeguards on its us

545. The Department wishes to ensure a more agile and flexible framework for certain health bodies that can adapt over time. It is aware ALBs want to work together more closely and the COVID-19 pandemic exposed the need to work flexibly. Building on this recent energy and innovation, it wants to provide a mechanism to support a more responsive, adaptive system than the current structure allows.

546. The impetus for these legislative proposals came from NHS England itself. In its report on implementing its Long Term Plan in February 2019, NHS England stated:

> "*We propose legislative changes to enable wider collaboration between ALBs by establishing new powers for the Secretary of State to transfer, or require delegation of, ALB functions to other ALBs*…" ([6])

547. The current landscape is a complex range of bodies overseeing the planning, commissioning, delivery and regulation of health and care services and vested in those bodies functions which had been the direct responsibility of Secretary of State. This has been a source of confusion at the front line of health and care dealing with often competing priorities and instructions from different organisations. This power would allow the Secretary of State to make changes and enable him to transfer and consolidate functions across these set ALBs as the need arises to ensure that the impact of any fragmentation is mitigated and that the bodies themselves do not have overlapping or competing roles.

548. A 2019 report by the House of Commons Health and Social Care Committee set out that the "national architecture of the NHS poses a barrier to more integrated, collaborative, and place-based working"[7]. It also observes that "joint working is limited by current legislative constraints". Having a power which increases the flexibility of the current set-up and landscape would help to mitigate this and support progress towards improved joint working across the system.

549. A key aim of the Department, which runs throughout much of the Bill, is to allow health bodies to work in a more integrated way and to be able to respond promptly and gain efficiencies whenever possible. These provisions assist with that aim and such an aim would be hampered if the Department had to wait for new primary legislation to move functions around to other relevant bodies. In many cases, it would be a small change

([6]) *Implementing the NHS Long Term Plan: Proposals for possible legislation*, February 2019, page 24, paragraph 82

[7] https://publications.parliament.uk/pa/cm201719/cmselect/cmhealth/2000/2000.pdf

between one ALB and another ALB's functions, which would not warrant a new piece of primary legislation.

550. The Secretary of State will remain accountable to Parliament at all times. Section 1(3) of the 2006 Act expressly states that "*The Secretary of State retains ministerial responsibility to Parliament for the provision of the health service in England*" and this remains unchanged by any proposals in the Bill. Therefore, the Department considers the moving around of functions will benefit efficiency but there will still be sufficient oversight both via regulations being subject to the affirmative procedure and the continued accountability of the Secretary of State.

Bodies covered by the power:

551. There is a short list of ALBs within the scope of the power. A number of health and care-related bodies are not included in this power due to the nature of their advisory, regulatory and/or public health functions. For example, the following are not covered by this power:

a) The UK Health Security Agency
b) The Medicines and Healthcare Products Regulatory Agency
c) The National Institute for Health and Care Excellence
d) The CQC
e) The Professional Standards Agency
f) The HSSIB (to be established in this Bill)

552. The relevant bodies covered by this power are all public bodies, sponsored by the Department and operate in the health sector and in many instances have complementary functions where there could be material benefit to joint delivery and/ or there could be back-office efficiencies created by transferring function or functions.

553. There are no immediate plans to change or transfer functions of the bodies in the system but the utility of having such flexibility in the future is key to why it is included in this Bill. As the health and care system adjusts to other changes, including those within the Bill to make systems more integrated, the flexibility to transfer powers in response may be required. Using primary legislation each time a function was to be moved would be very time-consuming, as would setting up any new ALBs. The power therefore provides a balance between adequate safeguards and the system being able to respond quickly in order to serve the public in the best way it can.

Precedent:

554. There is precedent for powers of the type proposed by this clause in the Public Bodies Act 2011. However, the powers in the Public Bodies Act 2011 went substantially further than the provisions in this Bill, in that they allowed for the abolition of bodies (without a transfer of their functions elsewhere) and applied to a wider range of bodies. The Human Tissue Authority and the Human Fertilisation and Embryology Authority were both subject to the transfer of functions power in the Public Bodies Act 2011 (Schedule 5 to that Act (as it came into force though now sunsetted)).

Limitations on the power:

555. The power to transfer functions may only be used when the Secretary of State considers that it would "improv[e] the exercise of public functions" having regard to the list of factors set out at subsections (2)(a) to (d) of clause 87. Further, the Secretary of State must always act consistently with his general duties set out in the 2006 Act, in particular sections 1A – 1F , when he makes decisions in relation to the health service, including, importantly, his duty to exercise his functions with a view to securing continuous improvement in the quality of services (section1A).

556. The power does not allow the Secretary of State to abolish a substantive function of a body, the power is simply to change the body that exercises the function. The power to abolish functions may only be used if it is consequential, supplemental or incidental to / upon a transfer (for example if a transfer created an overlap of functions exercised by the same body).

No power to abolish NHS England:

557. The clause contains a carve-out for NHS England from the consequential power to abolish a body that has been rendered redundant by a transfer of its functions to other bodies (this is provided at clause 87).The carve-out operates by providing that the Secretary of State may not in the first place provide for a transfer of functions that would, in his view, render NHS England redundant (see sub-section (3)). NHS England is the largest body in the list of relevant bodies. It was considered appropriate to be explicit, on the face of the Bill, that it could not be abolished using regulations.

Consultation requirement:

558. It is provided at clause 92 that prior to making regulations under either clause 87 or 88, the Secretary of State must consult:

a) Any body to which the draft regulations relate;

b) The devolved authorities, in the event that draft regulations would apply in the devolved nation in question and would be within the legislative competence of the devolved legislature, or relate to functions exercised by the devolved authority, and

c) Any other person whom the Secretary of State considers appropriate.

559. This will act a safeguard on the use of the power, ensuring that the Secretary of State does not make regulations without having obtained the views of key stakeholders involved beforehand.

Consequential, supplementary, incidental, transitional or saving provision amendments

560. This regulation making power can be used to make consequential, supplementary, incidental, transitional or saving provisions as provided for at clause 131. To provide

clarity as to what such provisions may look like in the context of this power the Bill sets out the power can used to:

- Modify functions of a relevant body;
- Modify the constitutional or funding arrangements of either body, or
- Abolish a body from which functions have been transferred, when that body has been rendered redundant by the transfer of functions.

561. These types of consequential and supplementary amendments could be needed to ensure a smooth transfer of functions.

562. It may be necessary to modify ancillary functions in order for a body to appropriately exercise the function which is being transferred (or delegated to it under clause 88) or abolish a function of the body where an overlap of functions has arisen as a result of a transfer. It is likely that this power will be used for relatively minor supporting functions and can only be used if the change is within the scope of clause 131 It may also be necessary to change the purpose or objective for which the body exercises a function since a body to which a function is transferred may have differing purposes or objectives to the body which previously exercised the function.

563. It may be necessary to modify constitutional arrangements of a body, for example, the name of the body to reflect new functions; to amend the requirements of the chair (including qualifications and procedures for appointment and functions); to change the members of the body (including the number of members, qualifications and procedures for appointment and functions) perhaps because different types of experience may be needed); or to change governing procedures and arrangements (for example, the role and memberships of committees and sub-committees of the body, to ensure that they exercise all of the necessary roles that may arise in relation to a new function).

564. It may also be necessary to modify the extent to which the body is funded by a Minister, and to confer a power on the body to charge fees for the exercise of a function due to the functions which have been transferred to it. Again this cannot be used to create new policy but would be available as a consequential or supplementary amendment to reflect the transfer of a function to the body under the Bill powers.

Powers of bodies and criminal offences

565. Subsection (4) of clause 89 provides that regulations may repeal and re-enact but cannot create:

- a power to make subordinate legislation
- a power of forcible entry, search or seizure
- a power to compel the giving of evidence
- a criminal offence

566. This is necessary in order that, where one of the relevant bodies exercises a power of the type above, or where a criminal offence relates to a body, it will be possible for the Secretary of State to provide for the power to be exercised instead by the body to which a function is being transferred. It is a strictly limited power because it cannot be used to

create any new powers of the types described above, or criminal offences, simply to repeal and re-enact them.

Power to amend devolved legislation

567. Subsection (6) of clause 89 provides a power to repeal, revoke or amend legislation of each of the devolved legislatures. This is necessary as there are references to the relevant bodies in devolved legislation which may need to be amended to refer to a new body to which a function is transferred. It is intended that this power be used only in this limited way, and indeed it may only be use when the need to use it is genuinely consequential upon the transfer or delegation of functions.

Justification for the procedure

568. The procedure for the making of regulations will be the affirmative procedure.

569. It is recognised that this is a relatively wide power that includes the power to make amendments to primary legislation, therefore it is appropriate that the affirmative procedure should be used. This will enable parliamentary scrutiny of any proposed regulations before they are made.

Clause 88 : Power to provide for exercise of functions of Secretary of State
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

570. This clause includes a regulation making power to allow the Secretary of State to delegate functions to a relevant body. This covers the functions of the Secretary of State that relate to the health service in England and any other functions that the Secretary of State may provide for a SpHA to exercise.

571. SpHAs are created by secondary legislation under the Secretary of State's power provided by section 28 of the 2006 Act and the Secretary of State may direct them to exercise his functions under section 7 of the 2006 Act. Under this clause regulations could be made so that the functions currently performed by SpHAs will be exercised by any of the above relevant bodies. The current SpHAs are::

a) **NHS Business Services Authority**
b) **NHS Counter Fraud Authority**
c) **NHS Blood and Transplant,**
d) NHS Litigation Authority (operationally known as **NHS Resolution**).

Justification for taking the power

572. SpHAs do not have functions of their own; they simply exercise the Secretary of State's functions on his behalf. Therefore the power is not to transfer their functions to one of the "relevant bodies", but for the Secretary of State instead to provide for functions that he may provide for a SpHA to perform, to be performed instead by one of the relevant bodies. The Secretary of State would likely revoke the delegation of the function to the SpHA previously exercising it. The power goes wider than existing functions exercised by current SpHAs. This is because such a limit could create an unhelpful and artificial split in the future should an SpHA be directed to perform additional functions under section 7 of the 2006 Act but those functions could then not be covered by this power whereas other functions of that same SpHA would be covered. The policy intention is to provide for flexibility across the health landscape and this includes embracing changes with SpHAs and allow for the delegation of Secretary of State functions where it may be beneficial to the health service. The power is capable of delegating the functions which the Secretary of State could direct a SpHA to do to any of the relevant bodies and the drafting of the power reflects this.

573. The policy underlying this provision is essentially the same as that of the clause above – namely that there is a need to be able to move functions between different bodies in the health service more speedily and flexibly than legislation currently allows. It is necessary for the same reasons as the power above..

574. The same safeguards in respect of consultation requirements and the limited number of relevant bodies that can be required to exercise functions apply to this power too. The test set out at clause 87 does not apply to this clause because this power relates to the delegation of functions by the Secretary of State, in circumstances where he retains responsibility for the exercise of the delegated functions, rather than an outright transfer of functions. It therefore differs from the power above and also the Public Bodies Act 2011 from which the original test derived. The Secretary of State must act consistently with his general duties set out in the 2006 Act, in particular sections 1A – 1F, when he makes decisions in relation to the health service, including, importantly, his duty to exercise his functions with a view to securing continuous improvement in the quality of services (section1A). This continues to be relevant when exercising this power too.

575. Clause 88 provides that regulations can make provision for consequential or supplementary amendments in respect of modifying functions of a relevant body or modifying the constitutional or funding arrangements of either body in the same way as noted under clause 87 above. However, the power to abolish a body is not needed. The Secretary of State has existing powers over SpHAs and therefore does not need specific provision allowing him to abolish a SpHA that is rendered redundant as a result of a transfer of functions here.

576. As we noted above, clause 89 further explains what may be done when modifying the functions, constitutional or funding arrangements of a body.

577. As explained above, this regulation-making power has the same ability and limits in respect of creating new powers of bodies and criminal offences as set out at clause 89 and explained above in relation to clause 87, as well as the ability to amend primary legislation and devolved legislation.

Justification for the procedure

578. It is proposed the procedure for the making of regulations will be the affirmative procedure.

579. It is recognised that this power includes the power to make amendments to primary legislation, therefore it befitting that the affirmative procedure should be used. This will enable parliamentary scrutiny of any proposed regulations before they are made.

Clause 90: Transfer schemes in connection with regulations
Power conferred on: Secretary of State (power to make transfer schemes)
Power exercised by: Scheme
Parliamentary procedure: None

Context and purpose

580. Upon the transfer of a function from one NDPB to another, or the delegation of one of the Secretary of State's functions to an NDPB, it is likely that assets, rights and liabilities previously held by the 'transferor' body will need to be transferred to the 'transferee' body. This clause provides that the Secretary of State may, in connection with regulations made under clauses 87 or 88 make schemes for the transfer of property, rights or liabilities from any body from which a function is transferred (or the Secretary of State, as may be necessary in connection with a delegation of the Secretary of State's functions), to any of the persons listed at subsection (10) as "appropriate persons".

581. A transfer scheme may amongst other things, create rights or impose liabilities in relation to property or rights transferred. It may make provision for shared ownership or use of property, make provisions about the continuing effect of things done by the transferor in respect of anything transferred etc.

Justification for taking the power

582. It is necessary to delegate the power to make transfer schemes, as it would not be practical to make specific provision in primary legislation in each case where a transfer of property and staff, and of the associated rights and liabilities, proves to be necessary. The need for transfers of property, rights or liabilities will only arise upon the use of the power under clauses 87 or 88 and therefore provision cannot be made at the time of this Bill for the transfers.

583. The schemes will be specific in nature and would be used in individual cases. Each scheme would apply only to the particular arrangement and particular property, rights

and liabilities in the scheme. The details cannot therefore be set out in primary legislation.

584. In most respects the transfer schemes envisaged in this clause are relatively standard. However, the Department acknowledges that there is a broader list of appropriate persons to whom an asset, right or liability might be transferred in the event of the use of this power, than merely the relevant bodies that are subject to the transfer of functions power. This is because there may be circumstances in which it would be appropriate for an asset, right or liability to be transferred to a person other than the body to which a function was being transferred.

Justification for the procedure

585. The schemes are concerned with administrative and operational details, and as is standard with transfer schemes in general, the Department considers that no Parliamentary procedure is required.

Clause 91 : Transfer schemes: taxation
Power conferred on: The Treasury
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

586. This clause provides that the Treasury may vary the way in which a relevant tax has effect in relation to—

a) anything transferred under a scheme under clause 91, or
b) anything done for the purposes of, or in relation to, a transfer under such a scheme.

Justification for taking the power

587. The Department's intention is that any transfer or assets, rights, or liabilities be tax neutral for the transferee and the transferor. In order to ensure that no taxes arise, and no changes to the tax position of either the transferee or transferor body arise, the Department has included a power for the Treasury to vary any relevant tax. There is a precedent for this type of power in section 25 of the Public Bodies Act 2011.

Justification for the procedure

588. As this power is only intended to be used for the purpose of ensuring that the effect of any transfer is tax neutral, it is not considered necessary that the regulations would need to be debated in Parliament. However, the transparency of regulations will allow Parliament to be made aware of any variations in tax. It is envisaged the power will be rarely used as health service bodies are exempt from many forms of taxation in any

event. The Department considers the negative procedure would be proportionate and appropriate in these circumstances.

PART 4

Powers relating to The Health Services Safety Investigations Body

Clause 95: Deciding which incidents to investigate – power to direct the HSSIB to investigate particular qualifying incidents, or qualifying incidents of a particular description
Power conferred on: Secretary of State
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

589. The HSSIB conducts investigations to identify risks to the safety of patients and address those risks by facilitating the improvement of systems and practices in the provision of NHS services or other health care services in England.

590. This clause confers a power on the Secretary of State to direct the HSSIB to investigate particular qualifying incidents, or qualifying incidents of a particular description. This direction may specify the date by which the HSSIB must publish its final report. A direction may be varied or revoked by subsequent directions.

Justification for taking the power

591. This power will ultimately help identify risks to the safety of patients and address those risks, by giving the Secretary of State a referral mechanism by which investigations can be initiated.

592. It is not possible to outline types of incident prospectively, or individual incidents, which should automatically be referred to the HSSIB for investigation and set these out in primary legislation. To do so would be inefficient. Instead, it is more appropriate for the Secretary of State to evaluate whether qualifying incidents which the HSSIB is not currently investigating, should be investigated.

593. The direction may provide for a person to exercise a discretion in dealing with any matter. There are circumstances in which allowing a person to exercise discretion would result in a more effective investigation, which would help improve the systems and practices in the provision of health care services in England. For example, the Secretary of State may direct the HSSIB to investigate the efficacy of PPE in the preventing the spread of COVID in hospitals, outlining that SAGE can specify a particular variant, or an item of PPE which should be the focus of the investigation.

594. The HSSIB may discontinue an investigation, should they wish to do so, this being a key limitation on the power being delegated.

Justification for the procedure

595. The Department considers a Parliamentary procedure unnecessary in the use of this power, as the HSSIB is the ultimate arbiter of whether an investigation will proceed, and therefore evaluates whether investigating a qualifying incident is justified.

596. It may be necessary for the Secretary of State to refer a qualifying incident to the HSSIB for investigation at short notice, and the time that would be taken by scrutiny of these referrals may be detrimental to patient safety.

Clause 96 : Criteria, principles and processes – duty to determine and publish criteria HSSIB will use in determining which incidents to investigate, the principles which will govern investigations, the processes to be followed in carrying out investigations and the processes for ensuring patient involvement
Power conferred on: The Health Services Safety Investigations Body
Power exercised by: Publishing criteria, principles and processes
Parliamentary procedure: None

Context and purpose

597. The HSSIB must determine and publish the criteria it will use in determining which incidents it investigates, the principles which govern investigations, the processes to be followed in carrying out investigations and the processes for ensuring that so far as reasonable and practicable, patients and their families are involved in investigations.

Justification for taking the power

598. The HSSIB will be better placed than the Department to determine these matters, owing to the operational experience of the Healthcare Safety Investigation Branch (HSIB) and (once established) the HSSIB's involvement in ongoing investigations. It is expected that the criteria, principles and processes will be more comprehensive than would be appropriate for primary legislation.

599. The criteria and principles are necessary as the HSSIB has the function of investigating qualifying incidents, the definition of which is intentionally broad. The Department believes that this approach best aligns with the aim of securing improvement in the provision of NHS services or other health care services in England. Therefore, the HSSIB will determine the process to follow in investigations. This must outline the time within which the HSSIB aims to complete investigations and the procedures and methods to be used in investigations, including the interviewing of persons. Owing to the wide variety of incidents which the HSSIB may investigate (see entry on j215b), the HSSIB may determine different processes of different descriptions of investigation. This will ensure that the HSSIB takes a consistent approach to investigations and seeks to conclude investigations in a timely manner.

600. The HSIB generally receives positive feedback from patients and their families who are involved in investigations, and therefore it would be beneficial for the HSSIB to build upon their success by determining how is best to involve patients and families in investigations.

Justification for the procedure

601. When the criteria, principles and processes are determined and revised, the HSSIB must consult the Secretary of State and any other persons the HSSIB considers appropriate. The criteria, principles and processes must be reviewed within three years of first publishing, and within five years thereafter. Therefore, the Department does not consider that any further Parliamentary scrutiny is required, given the operational nature of these documents.

Clause 107: Exceptions to prohibition on disclosure – power to make regulations authorising or requiring disclosure
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

602. The HSSIB undertakes investigations within a 'safe space' where the unauthorised disclosure of protected material is prohibited. The Bill creates certain criminal offences relating to unlawful disclosure. This encourages those involved in investigations to be open and honest, as there are only limited circumstances in which the information and material they provide can be disclosed to others. The integrity of the safe space is fundamental to effective investigations.

603. This clause outlines that the prohibition on disclosure does not apply to disclosure which is authorised, or required by Schedule 14, any other provision in Part 4 or regulations made by the Secretary of State. This confers a power on the Secretary of State, who may make regulations which authorise, or require, disclosure.

604. Within the regulation, the Secretary of State may provide for a person to exercise discretion in dealing with any matter.

605. These regulations may not require or authorise disclosures of protected material by reference to the qualifying incident to which the material relates. In addition, the disclosures must not breach obligations of confidence owed by the person making the disclosure or any other restrictions on disclosure.

Justification for taking the power

606. As unlawful disclosure is an offence, the power is required to ensure that the Secretary of State can appropriately define when disclosure from the 'safe space' is permissible.

607. It would not be possible to set out in primary legislation the extent of permissible disclosure. The HSSIB can investigate a wide variety of qualifying incidents, and through undertaking these investigations it may become apparent that it should be permissible for certain protected material to be disclosed. For example, the HSSIB could undertake investigations into the provision of mental health care to patients presenting at the emergency department; the detection and treatment of undetected ingested batteries in children; wrong patient details on blood samples and unintentional overdose of paracetamol in adults.

608. Given the broad scope of the HSSIB's investigation function, it is beneficial to allow some flexibility so the Secretary of State is able to amend the 'safe space' in light of stakeholder proposals, should the need arise.

609. Within the regulation, the Secretary of State may provide for a person to exercise a discretion in dealing with any matter. There will be circumstances in which another person exercising their discretion would better preserve the integrity of the 'safe space'. For example, if the Health and Safety Executive provides the HSSIB with advice to support an investigation, the Secretary of State could make regulations allowing for the disclosure of this advice, if the Health and Safety Executive believes it is in the public interest to do so. Here, the Health and Safety Executive would be better placed than the Secretary of State to determine whether it would be appropriate to disclose the protected material.

610. Schedule 14 and other provisions of Part 4 also outline where disclosure is permissible. Therefore, although the Secretary of State can make regulations, these will accompany the provisions within the Bill.

Justification for the procedure

611. In order for effective investigations to be conducted, the integrity of the 'safe space' must be preserved. Therefore, before disclosure of certain material is permitted, it must be properly considered whether this would impede the HSSIB's ability to investigate qualifying incidents. The affirmative procedure ensures that Parliament are able to scrutinise the proposed amendments properly.

Clause 110: Co-operation – duty to publish guidance about when a qualifying incident is to be regarded as related to another incident
Power conferred on: The HSSIB
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

612. Clause 110 requires the HSSIB to publish guidance about when a qualifying incident will be regarded as related to another incident for the purposes of the co-operation clause. A qualifying incident is an incident that occurs in England during the provision of health care services that has or may have implications for the safety of patients.

613. If either an incident is being investigated by a listed person and deemed to relate to a qualifying incident which the HSSIB is investigating, or the HSSIB and a listed person are investigating the same incident, the person and the HSSIB will be under a duty to co-operate with each other regarding practical arrangements for co-ordinating those investigations.

Justification for taking the power

614. When the same incident is being investigated by the HSSIB and a listed person, the duty to co-operate will apply. The guidance will affect whether certain incidents are 'related' to a qualifying incident, and therefore whether the duty to co-operate applies in these situations.

615. The HSSIB can undertake a wide variety of investigations (see entry on clause 107), and therefore it would be difficult to prospectively outline how narrow or broadly 'related to another incident' should be interpreted. If this is interpreted too broadly, it could result in the HSSIB and listed persons wasting resources for little to no benefit. If it is interpreted too narrowly, listed persons may not co-operate with the HSSIB and this could result in inefficiencies, such as the HSSIB requiring certain documents which are in the possession of a listed person. Delegating this power will result in better operational outcomes, and the HSSIB will be best placed to determine the content of the guidance.

Justification for the procedure

616. A Parliamentary procedure is considered unnecessary; it would be unusual for Parliament to scrutinise this type of guidance, and the Department does not considers there is a need to depart from this position.

Clause 113: Failure to exercise functions – power to give a direction to HSSIB about how it should carry out any of its functions
Power conferred on: Secretary of State
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

617. This clause confers a power on the Secretary of State to give a direction to the HSSIB about how it should carry out any of its functions. The power enables the Secretary of State to direct the HSSIB only if the Secretary of State considers that the HSSIB is failing or has failed to discharge any of its functions, or is failing or has failed to discharge any of its functions properly and the failure is significant. The HSSIB's failure to exercise any of its functions includes a reference to exercising it properly.

618. The Secretary of State can direct the HSSIB to discharge those functions in such a manner and such a time as may be specified in the direction. However, the direction

may not direct the HSSIB in relation to the outcome of a particular investigation. This is a safeguard to protect the independence of the HSSIB and avoid any perception that its conclusions and recommendations in relation to a specific investigation can be influenced by political pressure. The purpose of the power to direct is to enable the Secretary of State to intervene where widespread failure by the HSSIB can be demonstrated and is similar to the Secretary of State's powers in relation to other NDPBs in health, such the NHS England and CQC.

619. If the HSSIB fails to comply with a direction given under this clause, the Secretary of State may discharge the function that the direction relates to, or make arrangements for another person to discharge the function on behalf of the Secretary of State.

Justification for taking the power

620. The power is required to ensure that the Secretary of State can appropriately intervene if the HSSIB, a public body, fails to properly discharge its functions and that failure is significant. These directions can be varied or revoked by subsequent directions; this allows for the Secretary of State to only intervene so far as is necessary.

621. It would not be possible to set out in primary legislation exactly what intervention would be necessary in what circumstances, so this power provides the Secretary of State with flexibility to respond appropriately and quickly to any failures by the HSSIB. In most cases where the HSSIB appears to be failing to fulfil its functions this would be addressed through additional governance arrangements, for example through setting additional key performance indicators and additional accountability review meetings. However, a power to give a formal direction might be needed if HSSIB continue to fail to discharge its functions properly. For example, if the Secretary of State considered that the HSSIB was failing to progress a sufficient number of investigations to the extent that it was significantly failing to exercise its functions. In these circumstances, it may be appropriate for the Secretary of State to direct the HSSIB to progress a specified number of investigations within a specified period.

622. The Secretary of State has similar powers in relation to other ALBs, see for example:
    a) section 13Z2 of the 2006 Act in relation to the NHS England,
    b) section 71 of the 2012 Act in relation to Monitor (which will be merged by this Bill with NHS England) or
    c) section 82 of the 2008 Act in relation to the CQC or Healthwatch England.

623. The HSSIB exercises its investigation function to improve the systems and practices for the provision of health care services in England (including NHS services). Similarly, Monitor and the CQC both oversee patient care to ensure that it meets the required standard. Healthwatch England aims to improve health and social care by championing the views of individuals to relevant bodies in the hope of achieving change. These bodies contribute to ensuring that patients receive good quality care, and therefore it is important that they properly exercise their functions. Should they not do so, it is appropriate that the Secretary of State is able to step in, especially in light of the

Secretary of State's duty as to improvement in quality of services per section 1A of the 2006 Act.

Justification for the procedure

624. Where the HSSIB has failed or is failing to exercise any of its functions and the failure is significant, it may be necessary for a direction to be given quickly to ensure the functions are carried out properly without unnecessary delay.

625. A written direction from the Secretary of State is considered the most appropriate procedure for this power as it allows flexibility to determine the format of the direction based on the type of intervention that is necessary. In addition, the power is limited and relates only to ensuring existing functions are properly performed, it cannot be used to change the HSSIB's functions or to confer additional functions on the HSSIB.

Schedule 13 paragraph 18(2) – the Health Services Safety Investigations Body – accounts – power to give directions to the HSSIB regarding the content and form of its accounts and the methods of principles to be applied in the preparation of its accounts
Power conferred on: Secretary of State
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

626. Part 1 of Schedule 13 outlines the constitution of the HSSIB. This includes provisions which concern the HSSIB's accountability to the Secretary of State, including on financial matters. The Secretary of State may give directions to the HSSIB regarding the content and form of its accounts and the methods and principles to be applied in the preparation of its accounts.

Justification for taking the power

627. It is important that the HSSIB maintain accounts in an appropriate format. The format which these accounts should take, and the methods and principles which should be applied may be different for different circumstances. Therefore, this power of direction is considered the most appropriate way to achieve this flexibility.

Justification for the procedure

628. A Parliamentary procedure is not considered necessary given that accounting requirements for public bodies are technical matters and it is standard practice to use directions for this purpose.

Schedule 13, Part 2, Paragraph 22: Transfer Schemes – power to make one or more transfer schemes in connection with the establishment of the HSSIB
Power conferred on: Secretary of State

Power exercised by: Scheme
Parliamentary procedure: None

Context and purpose

629. When the HSSIB is established it will take over some of the functions of the Investigation Branch, which, is a division of the TDA. Property, rights, and liabilities, including in relation to contracts of employment, may need to be transferred from the TDA to the HSSIB.

630. These provisions confer a power on the Secretary of State to make one or more transfer schemes in connection with the establishment of the HSSIB. A transfer scheme allows for the transfer of any property, rights or liabilities of NHS England to the HSSIB. Transfer schemes provide a clear written record of the detail of the transfer. Paragraph 22 of Schedule 13 contains further provisions about the scope of the transfer schemes.

631. The power is similar to existing powers under the 2006 Act, for example section 14I provides a power for the National Health Service Commissioning Board (known as NHS England) to make a property transfer scheme or a staff transfer scheme in connection with the variation of the constitution of a CCG or the dissolution of a CCG.

Justification for taking the power

632. This delegated power is necessary to allow for provision to be made for the transfer of property and staff from the TDA to the HSSIB once the HSSIB is established and becomes operational. The details of such transfers, along with any associated rights and liabilities to be transferred, will be determined at that time.

Justification for the procedure

633. The Department considers a Parliamentary procedure unnecessary for the use of this power, since it would make provision for the property and staff of the TDA within the limits set by paragraph 22 of Schedule 13to the Bill.

634. There is a precedent for this approach, the powers referenced above for NHSE England to make transfers between CCGs, are not subject to a Parliamentary procedure.

Schedule 13 , Power to vary taxation – Part 2, paragraph 23 – power to make regulations varying the way in which a relevant tax has affect in relation to the transfer scheme under paragraph 22 of Schedule 13
Power conferred on: The Treasury
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

635. Paragraph 23 of Schedule 13 provides that the Treasury may vary the way in which a relevant tax has effect in relation to—
    c. anything transferred under a scheme under paragraph 22 of Schedule 13, or
    d. anything done for the purposes of, or in relation to, a transfer under such a scheme.

Justification for taking the power

636. The Department's intention is that any transfer of assets, rights, or liabilities be tax neutral for the transferee and the transferor. In order to ensure that no taxes arise, and no changes to the tax position of either the transferee or transferor body arise, the Department have been advised by HMRC that the transfer scheme provisions should include a power for the Treasury to vary any relevant tax.

Justification for the procedure

637. As this power is only intended to be used for the purpose of ensuring that the effect of any transfer is tax neutral, it is not considered necessary that there be significant parliamentary scrutiny of any variations in tax under this power. Indeed the power will need to be used relatively rarely, as health service bodies are exempt from many forms of taxation in any event. Therefore, the Department considers the negative procedure would be proportionate and appropriate.

Schedule 14, paragraph 8 – Prohibition on disclosure of HSSIB material: exceptions – power to publish guidance relating to protected material
Power conferred on: The HSSIB
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

638. This paragraph requires the HSSIB to publish guidance on when protected material should be disclosed under paragraph 2, 3 or 4, the types of protected material it might be appropriate to disclose in these circumstances and the processes which should be used when disclosing protected material in these circumstances.

Justification for taking the power

639. The production of guidance will help ensure that the HSSIB takes a consistent approach to disclosure in these circumstances, and follows appropriate procedures. As the integrity of the 'safe space' is fundamental for the HSSIB to undertake effective investigations, it is important that protected material is only disclosed when necessary. Unnecessary disclosure of protected material would weaken public trust in the HSSIB and may result in those involved in investigations being less willing to co-operate and share information.

640. This must be balanced against the potential benefits of disclosure under paragraph 2, 3 and 4. For example, a disclosure under paragraph 3 could result in a conviction for an

offence relating to investigations, which may deter others from obstructing an investigator.

641. The HSSIB will have the benefit of insight from the Healthcare Safety Investigation Branch, gained through their investigations, as well as operational experience (once established). Therefore, the HSSIB would be best placed to issue this guidance.

Justification for the procedure

642. A Parliamentary procedure is considered unnecessary given the operational nature of this guidance.

PART 5

International healthcare agreements

Clause 120 : International healthcare – substituting section 2 of the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 with a new section 2 – power by regulations to make provision for the purpose of giving effect to a healthcare agreement (including provision about payments)
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

Background

643. Reciprocal healthcare is a small and important element of general healthcare policy in the UK. Reciprocal healthcare agreements can support people from the UK to obtain access to healthcare in other countries (and vice versa for people from other countries who visit the UK). Reciprocal healthcare agreements support UK residents to access necessary healthcare when they travel abroad and can facilitate co-operation on planned treatment or other areas of healthcare policy. Reciprocal healthcare agreements are negotiated and agreed by the Government under prerogative powers and the agreements themselves need to be implemented in domestic legislation.

644. In 2019 Parliament enacted HEEASAA to establish a legal basis for the Secretary of State to fund and implement reciprocal healthcare, and share necessary data, after the UK left the EU. In anticipation of a possible no deal scenario, the HEEASAA contained powers to implement new bilateral arrangements with individual Member States and to establish detailed transitional unilateral arrangements to support certain people to access healthcare in an EEA state or Switzerland if no bilateral arrangement was in place.

645. On 24 December 2020, the UK signed the TCA with the EU. The TCA contains a Protocol on Social Security Coordination, which provides UK Nationals with access to a range of social security benefits, including reciprocal healthcare cover when they are in the EU. Consequently, detailed unilateral arrangements are no longer required.

646. The Government is now looking to strengthen the UK's relationships with countries across the globe and improve international healthcare cooperation.

647. During HEEASAA's passage through Parliament, the DPRRC noted that the delegated powers in the HEEASAA were wide. These amending provisions limit those powers so they reflect only what is necessary to implement Government policy now that the UK has left the EU and agreed the TCA.

648. Consequently, the Reciprocal Healthcare provisions in this Act amend HEEASAA to enable the Secretary of State to implement comprehensive reciprocal healthcare agreements with RoW countries.

649. Currently, the Secretary of State only has powers under HEEASAA to implement comprehensive reciprocal healthcare agreements within the EEA and Switzerland. The limited territorial scope of the powers in HEEASAA mean that the Secretary of State does not have the necessary powers to implement reciprocal healthcare agreements with ROW countries, including, for example, British Overseas Territories and Crown Dependencies, other than the ability to exempt individuals from charges for relevant NHS services.

650. As a result, although the UK has a number of reciprocal healthcare agreements with countries outside the EU, such as Australia and New Zealand, they are limited in scope because of the absence of financial reimbursement or data sharing powers. For example, under the terms of reciprocal healthcare agreements the UK has with ROW countries, UK nationals are able to access emergency treatment should they require it, however, access to haemodialysis for kidney patients is restricted or not included within the scope of these agreements.

651. The provisions expanding HEEASAA to RoW countries will enable the Secretary of State to make regulations for the purpose of giving effect to healthcare agreements, including provision for the reimbursement of healthcare costs.

652. Further, the amendments to HEEASAA will enable the Secretary of State to make discretionary payments, in exceptional circumstances, but only in countries with which the UK has a reciprocal healthcare agreement. This remains a necessary power which will allow the Secretary of State to support UK nationals abroad where due to exceptional circumstances they require to access healthcare abroad but fall outside the scope of a reciprocal healthcare agreement.

653. Recognising concerns raised by the DPRRC during the passage of HEEASAA, the amendments also limit the breadth of the powers so that they are no wider than necessary to implement reciprocal healthcare agreements in the future. In particular, the amendment removes the power to implement unilateral healthcare schemes.

The amendments

654. Clause 120 amends the HEEASAA to enable the Government to implement comprehensive reciprocal healthcare agreements with countries outside of the EEA and Switzerland.

655. Subsections (3) and (4) remove the wide power to make healthcare payments in section 1 of HEEASAA and the broad power to make regulations in relation to healthcare and healthcare agreements in section 2 of HEAASAA and replaces it with a narrower healthcare agreements and payments regulation making power. The effect of this substitution is that the Secretary of State will be able to make regulations to pay for healthcare provided outside the United Kingdom where the payments give effect to a

healthcare agreement (new section 2(1) of HEEASAA). The exact arrangements which will be provided for under any future reciprocal healthcare agreements is a matter for negotiations.

656. The Secretary of State will also be able to make regulations for the payment of healthcare provided in another country where the healthcare is outside the scope of a healthcare agreement but only if the Secretary of State thinks the payment is justified by exceptional circumstances and the healthcare is provided in a country with which the UK has a healthcare agreement (new section 2(2) of HEEASAA). For example, this discretionary power could be exercised to pay for a specific treatment, which falls outside the scope of a healthcare agreement.

657. The regulation making powers under new section 2 can also be used to confer or delegate functions to a public authority and to make administrative arrangements.

658. Significantly, the substituted section 2 removes the existing section 2 power to make regulations to establish detailed unilateral healthcare arrangements (section 2(1)(a) and (b) of HEEASAA). These powers were created to support people to access healthcare in the EEA and Switzerland in the event of a no deal EU Exit. As the United Kingdom has now agreed social security coordination provisions covering healthcare in the EU in the Withdrawal Agreement and the TCA, this measure is no longer needed.

659. The amendments to HEEASAA will also extend the existing data sharing provisions in section 4 of HEEASAA to RoW countries to provide a legal basis for facilitating data processing to support the making of payments and the giving effect to healthcare agreements.

Justification for taking the power

660. As with the current section 2 of HEEASAA, the substituted section 2 will enable the Secretary of State to provide for administrative arrangements, the conferral and delegation of functions to public authorities and a power to give directions to a person about the exercise of any functions exercisable under regulations. As is evidenced by the Healthcare (European Economic Area and Switzerland Arrangements) (EU Exit) Regulations 2019 (the HEEASAA Regulations), these regulations are by their nature technical, operational and detailed and so better suited to secondary legislation.

661. The clause also removes the broad payment power in s.1 HEEASAA and replaces it with a power to make regulations to make provisions for healthcare payments (new section 2(1) and (2). This will ensure, to the benefit of those using the legislation, that any payment provisions, administrative arrangements and conferral of functions will be in the same place i.e. in the same set of regulations.

Justification for the procedure

662. The Department considers that, as with the current section 2 power, the negative procedure affords the appropriate level of scrutiny in the case of regulations under clause 120 which substitutes section 2.

663. Substantive provisions about access to healthcare abroad will be contained in reciprocal healthcare agreements, such as the Withdrawal Agreement and the Protocol on Social Security in the TCA. The Government negotiates and agrees reciprocal healthcare agreements under the Royal Prerogative.

664. This clause contains limited powers to make technical and operational regulations to implement those agreements. The regulations are unlikely to contain policy issues that require in depth Parliamentary debate and consideration.

Regulation of local authority functions relating to adult social care

Clause 121: Regulation of local authority functions relating to adult social care - powers of direction enabling the Secretary of State to direct the CQC to revise indicators of quality and a methodology statement, both of which are to be used for the purposes of assessments carried out by CQC under new section 46A.
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

665. Clause 121 amends Chapter 3 of Part 1 of the 2008 Act to extend the application of existing duties and powers of the CQC and the Secretary of State in relation to adult social care.

666. Clause 121 inserts new section 46A (reviews and performance assessments: local authorities) into the 2008 Act. It amends sections 46, 48, 50 and 60 of the 2008 Act to extend their application to include reviews and performance assessments of local authorities carried out by CQC under new section 46A. Under section 46A, CQC must review and assess the performance of English local authorities in carrying out their 'regulated care functions'.

667. Section 46A(5) of the 2008 Act requires CQC to determine, and from time to time revise, indicators of quality for the purposes of the assessment under this section of the performance of relevant English local authorities. CQC must obtain the approval of the Secretary of State in relation to the indicators.

668. Section 46A(6) is a delegated power that allows the Secretary of State to direct CQC to revise indicators of quality under section 46A(5).

669. Section 46A(8) requires CQC to prepare, and from time to revise, a statement which sets out the methodology to be used for reviews to be carried out under section 46A, as well as the frequency and period to which the reviews relate. CQC must obtain the Secretary of State's approval in relation to the statement.

670. Section 46A(9) is a delegated power that allows the Secretary of State to direct CQC to revise the statement under section 46A(8).

Justification for taking the powers

671. CQC will be able to revise the indicators of quality and the statement 'from time to time' and must obtain Secretary of State approval in relation to the revisions. However, a power of Direction is also needed to ensure that CQC will be required to revise them should the Secretary of State wish them to do so. This might be needed, for example, in the event that the Secretary of State considers that the indicators or the statement need to be revised in response to a shift in priorities or a specific event such as a pandemic.

Justification for the procedure

672. The direction would be given in writing to CQC and would not be subject to any Parliamentary procedure. The power to direct CQC should be exercised under section 46A so as to allow the Secretary of State to retain control over quality indicators and the statement whilst also requiring CQC involvement in the revision of them where the Secretary of State directs.

673. A written direction from the Secretary of State is considered to be the most appropriate procedure for these powers as it allows flexibility for quality indicators and the statement to be revise as the Secretary of State considers necessary without the need for Parliamentary scrutiny. The powers are limited and relate only to ensuring existing functions are properly performed. They cannot be used to change CQC's functions or to confer additional functions on CQC. The scope and nature of CQC's functions in relation to this particular section (new section 46A) would already have been considered by Parliament during the passage of the Bill. These powers for the Secretary of State to direct CQC are limited to the revision of quality indicators and the statement for the purposes of performance assessments.

Clause 121 : Regulation of local authority functions relating to adult social care - power enabling the Secretary of State to make regulations prescribing which local authority functions in Part 1 of the Care Act 2014 will be subject to review by the CQC under new s46A, and to what extent they will be reviewed.
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

674. Clause 121 amends Chapter 3 of Part 1 of the 2008 Act to extend the application of existing duties and powers of the Care Quality Commission (CQC) and the Secretary of State in relation to adult social care.

675. Clause 121 inserts new section 46A (reviews and performance assessments: local authorities) into the 2008 Act. It amends sections 46, 48, 50 and 60 of the 2008 Act to extend their application to include reviews and performance assessments of local authorities carried out by CQC under new section 46A. Under section 46A, CQC must review and assess the performance of English local authorities in carrying out their 'regulated care functions'.

676. Section 46A(2) provides that 'regulated care functions' means such functions under Part 1 of the Care Act 2014 (functions relating to adult social care in England) as may be prescribed.

677. Section 46A(3) provides that regulations under subsection (2) may prescribe (a) all functions of relevant English local authorities under Part 1 of the Care Act 2014 or some of their functions under that Part; (b) the whole of a function or a particular aspect of it.

Justification for taking the power

678. English local authorities carry out a wide range of functions under Part 1 of the Care Act 2014. The Secretary of State has a delegated power to determine which specific local authority functions will be the subject of review and performance assessments by CQC under new section 46A. As the functions to be reviewed and assessed are likely to change from time to time, prescribing those functions in regulations will give the Secretary of State the appropriate flexibility to decide which functions should be reviewed and to what extent in any given period.

679. This regulation-making power is modelled on existing powers contained in section 46(1) and (2) of the 2008 Act in relation to CQC's review and performance assessment duties under section 46. That delegated power enables the Secretary of State to make similar provision through regulations about the type of regulated activities to be reviewed and the extent to which they may be reviewed. The Department considers therefore that the use of delegated legislation in this context is not likely to be controversial and follows existing precedent for reviews of this kind;

680. The regulation-making power is limited to the matters that the Secretary of State wishes to specify and no further.

Justification for the procedure

681. By virtue of section 162(1) of the 2008 Act, regulations made under this power will be subject to the negative parliamentary procedure.

682. The Department considers that the negative parliamentary procedure is appropriate and sufficient since regulations will make provision only in respect of local authority functions already set out in Part 1 of the Care Act 2014.

Social care services: financial assistance

Clause 122 Provision of social care services: financial assistance, amending section 153 into the Health and Social Care Act 2008 – power direct certain NHS bodies performing functions only or mainly in respect of England to exercise any function of the Secretary of State in relation to section 149(1) and (2) and new section 149(1A).
Power conferred on: Secretary of State in relation to England
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

683. Clause 122 amends sections 149, 151, 153, 154 and 155 of the 2008 Act. The existing legislative power set out in section 149 of the 2008 Act (and associated sections) allows the Secretary of State to make payments to, or for the establishment of, not-for-profit providers of Social Care in England. This power will be amended to bring all social care providers within scope, regardless of whether they are profit-making or not-for-profit bodies. The amendments in section 153 will also allow the Secretary of State to direct certain NHS bodies in England to carry out functions of the Secretary of State in relation to financial assistance under section 149. The making of arrangements to do so would come under section 154.

684. The proposed clause, inserting new section 149(1A) into the 2008 Act will allow the Secretary of State to provide financial assistance (in the form of loans, grants, purchases of share capital) to any social care provider in England in the same way the current powers allow for financial assistance to not-for-profit providers. Further, new section 149(1A) will now also provide for the Secretary of State to give financial assistance to *"bodies which are engaged in the provision to other persons of services, that are connected with the provision in England by those other persons of social services."*. New section 149(1B) limits the scope of assistance under new section 149(1A) to social care services being provided in England.

685. The clause will enable the Secretary of State to not only make direct payments (by way of financial assistance) to social care providers but will also allow for this power to be delegated under new section 153(2) whereby the Secretary of State may direct any Special Health Authority in England, to exercise any functions of the Secretary of State in relation to financial assistance under section 149(1A).

686. Section 153 (Directions to certain NHS bodies) is a substitute provision, retaining the Secretary of State's existing powers of Direction in relation to payments to health service bodies under section 149 and extending the Secretary of State's powers of Direction in relation to payments to social care providers under new section 149(1A). Section 153 provides that the Secretary of State in subsections (1)–(4) may direct certain NHS bodies performing functions only or mainly in respect of England to exercise any function of the Secretary of State in relation to section 149(1) and (2) and new section 149(1A).

Justification for taking the power

687. The Secretary of State's power of direction under section 153 will allow the Secretary of State when it is required, to direct certain bodies to carry out the Secretary of State's function. Section 153(1) has been narrowed to enable directions to specified bodies, (the NHS Trust and Special Health Authority in England) to carry out Secretary of State's functions in relation to financial assistance to health service bodies (under section 149(1)). Section 153(2) similarly enables Secretary of State to direct Special Health Authorities to carry out Secretary of State's functions in relation to financial assistance to social care providers (under section 149(1A)). It is difficult to prescribe each circumstance in the Bill as the Secretary of State will wish to retain operational flexibility to direct certain bodies to exercise the Secretary of State's functions.

688. Section 153(3) and (4) enable the Secretary of State to direct certain bodies to carry out the Secretary of State's functions in relation to financial assistance so far as the financial assistance payments relate to the establishment of new health service or social care providers. Directions would allow the Secretary of State the flexibility to direct these bodies to carry out the Secretary of State's functions if that was thought to be appropriate in the circumstances.

689. The direction making power under section 153(5) is necessary to allow the the Secretary of State the flexibility and discretion to further direct bodies who the Secretary of State directs to exercise his functions under section 153 about the exercise of those functions.

Justification for the procedure

690. As the delegated power being relied upon is a Direction making power, this will not require any parliamentary procedure. The justification for this is that a Direction is thought to be the most suitable method for Secretary of State to delegate the function of providing financial assistance. The power concerns the identity of the persons to whom the function of the Secretary of State is to be delegated, rather than the power itself, which has already been scrutinised by Parliament. This person exercising the function may change over time and therefore flexibility is needed but parliamentary scrutiny of that flexibility is not thought to be necessary. The Secretary of State's delegation of such power is likely to be non-controversial if the power is delegated to bodies already carrying out existing functions.

Regulation of health care and associated professions

Clause 123: Regulation of health care and associated professions – amending section 60 of the Health Act 1999, powers to make changes to legislation regulating health care professions.
Power conferred on: Her Majesty
Power exercised by: Orders in Council
Parliamentary procedure: Affirmative

Context and purpose

691. Clause 123 extends the scope of section 60 and Schedule 3 of the 1999 Act.

692. Section 60(1) permits modification to the regulation of existing regulated healthcare professions and for the introduction of healthcare professions into statutory regulation. An Order made under section 60 may repeal, amend, replace or revoke any enactment or instrument (subject to Schedule 3 of the 1999 Act). The Government must consult on draft Orders prior to them being laid before Parliament. The Orders are subject to the affirmative parliamentary procedure (see section 62(9) of1999 Act).

693. Schedule 3 specifies matters generally within the scope of section 60 orders, matters outside the scope of section 60 orders, the manner in which section 60 powers should be exercised and the preliminary procedure for making the orders.

694. Clause 123 will extend the scope of section 60 and Schedule 3 of the 1999 Act so that:
    a) where it appears that a regulated healthcare profession no longer requires regulation for the purposes of public protection it can be deregulated by an order in council;
    b) a regulatory body can be abolished by an order in council where the profession(s) concerned have been deregulated as above or will continue to be regulated by another regulatory body;
    c) groups of workers, whether or not they are generally regarded as a profession, can be brought into regulation;
    d) reserved functions of regulatory bodies can be delegated to other regulatory bodies by an order in council. These reserved functions are maintaining a register of members, determining standards of education and training and giving advice about standards of conduct and performance, and administering the fitness to practise function.

695. In addition, the clause makes provision updating the list of legislation regulating the health care profession which are subject to modification under section 60.

696. The purpose of these provisions is to create a more flexible and proportionate professional regulatory framework that is better able to protect patients and the public. These provisions will make it easier to ensure that the appropriate professions are regulated and that the level of regulatory oversight is proportionate to the risk to the public.

Justification for taking the power

697. Delegated powers under section 60 have been used on numerous occasions to legislate for the regulation of healthcare professions for in excess of 20 years and are considered established practice.

698. The legislation governing the regulation of health care professions is best amended by means of secondary legislation in order to allow regulatory bodies to be flexible and responsive to the changing needs of the healthcare environment, to support the development of a diversifying workforce and to protect the public effectively.

699. A number of technological, scientific and policy factors can affect whether or not a healthcare profession (or group of workers) may require regulation for the purpose of the protection of the public. A requirement to pass primary legislation for their introduction or removal from regulation would be disproportionate and unnecessarily costly.

700. Where it becomes necessary for a group of workers to be brought into regulation for the protection of the public, it is in the public's interest for this to be done at speed. For instance, a series of reviews into patient safety recently made findings of failings amongst healthcare managers, the new powers could bring these managers into regulation with more immediate effect. More detail on this contextual background can be found in the response to the recent consultation on promoting professionalism, reforming regulation.[8]

701. The current process for abolishing a regulatory body can be complex, lengthy and costly. For example, the initial decision to abolish the Hearing Aid Council was made in 2005[9] but the legislation to abolish the council was only introduced in 2007 and passed in 2008[10]. The functions of the council were fully transferred to the Health and Care Professions Council in 2010. The introduction of a power to deregulate via secondary legislation will ensure that regulatory bodies can be abolished at pace in future.

702. The exercise of the power to delegate functions to other regulatory bodies can include highly technical detail and would be an entirely administrative matter. It would therefore be inappropriate to do this via primary legislation as it would only serve to overload the statute book and could be a significant burden on parliamentary time.

703. There are existing safeguards in place restricting the exercise of section 60 powers; there is a duty to consult the appropriate stakeholders and other appropriate persons on a draft order (see paragraph 9 of Schedule 3 of the 1999 Act) and the affirmative parliamentary procedure is used for all section 60 orders in council as discussed below.

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8 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/820566/Promoting_professionalism_reforming_regulation_consultation_reponse.pdf

9 *Reducing administrative burdens: effective inspection and enforcement*, Hampton, March 2005

10 The Health and Social Care Act 2008 c.14 repealing the Hearing Aid Council Act 1968 c. 50

Justification for the procedure

704. Orders in council made under section 60 of the 1999 Act are subject to the affirmative parliamentary procedure and are therefore debated and approved by both houses of Parliament. Each of the powers discussed at paragraphs 688 to 693 above will remain subject to this procedure.

705. Section 6(1) of the 1999 Act is a 'Henry VIII power' in that it enables changes to be made to Acts of Parliament using secondary legislation. The additional provisions in this Bill under section 60 will extend the scope of the existing Henry VIII powers; therefore the affirmative procedure is necessary to ensure adequate parliamentary scrutiny and oversight in their use.

706. This procedure is also appropriate as the powers under this section relate to the regulation of healthcare professions. This area concerns significant risk to public safety and is therefore of great public interest and warrants such a degree of scrutiny.

707. There are also existing safeguards, mentioned at paragraph 700 above, that help limit inappropriate use of these powers. There are additional legal tests for the deregulation of a profession (i.e. it is not required for the protection of the public) and for the abolition of a regulatory body (it may only be exercised where the profession it regulates has been deregulated or is regulated by another regulatory body). Thus, there are clear boundaries to the executive's discretion in using the power.

Medical Examiners

Clause 124 : Medical examiners – inserting new subsection (A2) to section 19 of the Coroners and Justice Act 2009 - power for Secretary of State to issue directions to an NHS body concerning medical examiners
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

708. This clause confers a duty on the Secretary of State to take such steps as the Secretary of State considers appropriate for the purpose of ensuring that sufficient medical examiners are appointed, sufficient funds and other resources are made available to enable them to discharge their functions, and to ensure that their performance is monitored. For the purposes of discharging this duty, the clause provides the Secretary of State with a power to issue directions to an NHS body.
709. The direction may:-
    a) require an NHS body to appoint or arrange for the appointment of one or more medical examiners;
    b) concern the funds and other resources that are to be made available to a medical examiner employed by an NHS body;
    c) concern the steps taken by an NHS body to monitor the performance of a medical examiner; or
    d) concern the steps to be taken by an NHS Body to monitor the performance of functions by another NHS body in relation to a medical examiner.

    This, for example, enables one NHS body to be directed to make funds available to a medical examiner employed by another NHS body, or to be directed to perform oversight functions in relation to another NHS body. This is because the NHS body to whom a direction is given will not necessarily be the body employing the medical examiner.

Justification for taking the power

710. Although the Secretary of State is the most appropriate person on whom the duty should rest, he will not be involved in the appointment of medical examiners at an operational level, because they will sit within the structure of the NHS. Although not all trusts and foundation trusts will appoint medical examiners, they will all have access to one. NHS Improvement, working jointly with NHS England, will then appoint regional Medical Examiners who have an oversight function alongside the National medical examiner appointed by the Secretary of State. The power to direct NHS bodies will enable the Secretary of State to ensure that the bodies with operational control over medical examiners will take the steps necessary for the different parts of the duty to be met. It will enable the Secretary of State to respond quickly and flexibly to meet the

requirements, which might be different in different parts of the country or between different NHS bodies.

Justification for the procedure

711. The direction would normally be given in writing to an NHS body, as defined in clause 90(6) and would not be subject to any Parliamentary procedure. Where an NHS body has failed or is failing to exercise any of its functions in relation to the appointment of medical examiners, it may be necessary for a direction to be given quickly, to ensure the functions are carried out properly without unnecessary delay.

712. A direction from the Secretary of State is considered to be the most appropriate procedure for this power as it allows flexibility based on the type of intervention that is necessary. The power is limited and relates only to ensuring that the Secretary of State is able to discharge the duties set out in clause 90(2) regarding the appointment of medical examiners. It cannot be used to set out or amend the terms of a medical examiner's appointment or their functions (for which there is already a separate regulation making power) or to confer additional functions on an NHS body.

Advertising of less healthy food and drink

Clause 125: Advertising of less healthy food and drink

Context and purpose of Overall Policy

713. As part of the tackling obesity strategy the Government committed to taking further action to protect children from exposure to foods high in fat, sugar or salt ("HFSS") on TV and online.

714. Current advertising restrictions for HFSS products during children's TV and other programming of particular appeal to children are set out in statutory guidance known as the BCAP code (for broadcasting). Similar non statutory guidance for online services are set out in the CAP code. In spite of the restrictions, children continue to be exposed to a significant amount of unhealthy food adverts on TV, and online. These adverts can affect what and when children eat and shape their preferences from a young age

715. The provisions are designed to reduce children's overconsumption of HFSS products. Obesity is associated with reduced life expectancy, and it is a risk factor for a range of chronic diseases, including cardiovascular disease, type 2 diabetes, some cancers, liver and respiratory disease.

716. The consultation documents "Introducing further advertising restrictions on TV and online for products high in fat, sugar and salt (HFSS)" and "Introducing a total online advertising restriction for products high in fat, sugar and salt (HFSS)" set out the policy ambition that led to these provisions being introduced.

717. The proposal is to amend the Communications Act 2003 to restrict advertising for less healthy food and drink products on (a) television programme services (subsection (1)), (b) on-demand programme services ("ODPS") (subsection (2)) and (c) the internet (subsection (3)).

718. The provisions dealing with advertising on television programme services and ODPS introduce a watershed between 5.30am and 9pm, during which adverts for less healthy food and drinks cannot be shown. The provisions dealing with online advertising introduce a restriction on paid-for advertising of less healthy food and drink products online.

719. New sections 368Z15 to 368Z17 inserted into the Communications Act 2003 provide for an enforcement mechanism, financial penalties and a power to demand information for an investigation into whether the provisions have been breached.

720. The delegated powers are designed to allow government policy to evolve in response to changing standards in industry regarding broadcasting, online services and viewing

habits, as well as developments in food technology, scientific knowledge concerning nutrition priorities and changing social and economic circumstances.

Television programme services

Paragraph 1 of Schedule 16 inserts new section 321A into the Communications Act 2003: **Objectives for advertisements: less healthy food and drink**
Power conferred on: Secretary of State / OFCOM
Power exercised by: Regulations / setting of standards
Parliamentary Procedure:

Section 321A(1) Negative
Section 321A(2) (b) Negative
Section 321A(4)(c) Negative
Section 321A(4)(e) Negative
Section 321A(5) Affirmative

Context and Purpose

721. The new section 321A relates to television programme services and enables the Secretary of State to restrict the advertising of identifiable less healthy food and drink products on television programme services. This requires OFCOM to set standards in relation to the prohibition of advertisements for an identifiable less healthy food or drink product on television programme services provided between 5.30 am and 9.00 pm.

722. Section 321A contains five separate regulation-making powers. They are as follows:-
   i. Clause 321A(1) requires OFCOM to set standards in relation to the prohibition of advertisements for an identifiable less healthy food or drink product.
   ii. Section 321A(2)(b) confers a regulation-making power upon the Secretary of State to exempt categories of advertisements from the restrictions which will flow into the Standards produced by OFCOM under section 321A(1). This power is subject to consultation under section 321A (3).
   iii. Section 321A(4)(c)(i) allows a product to be classified as “less healthy” if it falls within a description specified in regulations made by the Secretary of State.
   iv. Section 321A(4)(e) confers a power on the Secretary of State to define “a food or drink small and medium sized enterprise “SME” .
   v. Section 321A(5) provides that the Secretary of State can make regulations to amend the meaning of “the relevant guidance” which is currently defined at section 321A(4)(d). This enables amendments to be made to the technical guidance that assists manufacturers and advertisers with identifying food and drink in scope of the regulations.

Justification for taking the power

723. Section 321A(1) The requirement to set standards enables OFCOM to remain responsive and flexible to changes. It will help to ensure that the regime remains effective and proportionate. This power is limited and its scope is clearly set out in primary legislation.

724. Section 321A(2)(b) The power will enable the Secretary of State to respond swiftly to developments in technologies and changes in the industry as it develops. The policy is one that is likely to evolve with industry making changes to its products to address health concerns. This power provides the ability to make other exemptions to the prohibition to recognise those changes and developments. Any such use of the power would first be subject to a duty to consult, so any exemption introduced by the power will have been consulted on and will be well considered. It was not considered appropriate or possible to set out all exemptions on the face of the bill due to the constantly evolving nature of the medium which is being regulated.

725. Section 321A(4)(c) The Government conducted an extensive consultation with stakeholders, which showed that there was a general desire for flexibility given the rapid developments in this industry. A delegated power enables the Secretary of State to adapt the restrictions in the light of feedback from stakeholders. This proposed power is intended to provide for legal certainty and flexibility in introducing regulations. The use of delegated legislation will allow the government policy to evolve promptly in response to ongoing developments in scientific knowledge and food standards and changing environmental priorities and changing social and economic circumstances.

726. Section 321A(4)(e) is required to give effect to section 321A(2)(a), which provides an exemption from the prohibition under section 321A(1) advertisements included in television programme services as a result of arrangements made by a food or drink SME. This ensures that burdens are minimised for small businesses where the impact of the policy is greater on revenue streams. This will ensure that the restrictions will be justifiable and proportionate. The power under section 321A(4)(e) provides the definition of an SME for these purposes. This allows flexibility for the criteria to be adjusted with changing economic conditions. For example, the regulations might initially provide that an SME has fewer than 250 employees, but at a later date a higher or lower number might be more appropriate.

727. Section 321A(5) provides a flexible power to keep in step with changes to technical guidance regarding less healthy food. Matters concerning scientific and industry based knowledge on nutritional matters are likely to require technically detailed provisions which would not be appropriate for primary legislation. The Department foresees that it may need to change guidance in response to scientific, economic and other conditions affecting specific food sectors. For example, changes in science concerning nutrition which may touch on issues such as recommended daily allowances for sugar and salt intakes. It is not possible to predict precisely what those changes should be. This power will additionally allow for consistency across Government obesity policies if the guidance were to be update. Given the pace of developments in technology and the conduct which

might need to be undertaken by businesses in order to keep up with these developments, it is appropriate that the details of the technical guidance is contained in secondary legislation. A flexible delegated power is therefore sought in the Bill to effect these changes in response to sector specific needs and requirements as they arise.

Justification for the procedure

728. The requirement for OFCOM to set standards by virtue of section 321A(1)(b) is not subject to any additional parliamentary procedure. There is precedent for this kind of requirement, for example section 319 of the Communications Act 2003.

729. The Department considers that the negative procedure ia an appropriate level of parliamentary scrutiny for regulations made using the powers described above because amendments are likely to be largely technical in nature.

730. Sector-specific exemptions made under section.321A(2)(b) exempting categories of advertisements from the restrictions should not give rise to any controversial issues as use of the power would be subject to a duty to consult and the power allows for further exemptions to be made to restrictions to take account of the evolving nature of the policy and future changes in food standards. There will be transparency due to consultation and the provisions of regulations which Parliament can still consider under the negative procedure.

731. Provisions made under section 321A(4)(c) provide for a negative procedure. It is desirable for the Secretary of State to be able to amend the definition in accordance with future changes in food standards. Moreover, any change to the meaning of "the relevant guidance" will be subject to the affirmative procedure. Accordingly, this limits the delegated power under this sub-section and allows Parliament to scrutinise the any wider changes proposed in respect of a guidance change but limits the need for Parliamentary time in relation to a more technical or scientific based change in respect of what may be considered "less healthy foods".

732. Provisions made under section 321A(4)(e) for defining an SME will largely be of a technical or administrative nature. Therefore, the Department considers the negative procedure is appropriate. Given the limitations on this power and the technical nature of amendments, there are unlikely to be policy issues that would merit the use of Parliamentary time for debates but it is important to ensure transparency and therefore regulations have been proposed which the associated scrutiny that allows.

733. The Department considers that the negative procedure in respect of the above regulations also enables regulations of a technical nature to be brought into force quickly following the consultation procedure. This will keep the regime up to date.

734. Provisions made in regulations under section 321A(5) will largely be of a technical or administrative nature. The Department considers that the affirmative procedure should apply where the power is exercised to modify primary legislation (as in this case). This

ensures that such regulations are afforded the appropriate degree of parliamentary scrutiny when changes to primary legislation are made.

735. It would also be important for Parliament to debate the implications of any changes to technical guidance that may impact on the food in scope of the policy. The exercise of this power may have important budgetary implications on businesses caught by the restrictions. It is therefore important that the consideration of the effect on food manufacturers, broadcasters and providers of online services is fully debated, given the current significance of the guidance to the policy.

On-demand programme services

***Paragraph 2 of schedule 16 inserts new section* 368FA: Advertising: less healthy food and drink in Communications Act 2003**
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Subsection 368FA(3), (5)(c)(i) and (5)(e): negative and subsection 368FA(6): affirmative

Context and Purpose

736. **New section 368FA** relates to on-demand programme services. It is needed to enable the Secretary of State to make regulations in relation to the advertising of less healthy food and drink in relation to that medium.

737. **Section 368FA** contains four regulation making powers in a similar way to the television programme services section as set out above. They are as follows:-

i. **Section 368FA(3)** confers the Secretary of State with powers to exempt other categories of advertisements from the restrictions where appropriate.
ii. **Section 368FA(5)(c)(i)** confers the Secretary of State with powers to detail which food categories fall within the scope of the regulations.
iii. **Section 368FA(5)(e)** confers a power on the Secretary of State to define “food or drink SME” for the purpose of this clause.
iv. **Section 368FA(6)** confers a power on the Secretary of State to define “the relevant guidance”.

Justification for taking the power

738. Section 368FA(3) As with the corresponding provision in respect of television programme services, the power will enable the Secretary of State to respond swiftly to developments in technologies and changes in the industry to this policy as it develops. The policy is one that is likely to evolve with industry making changes to its products to address health concerns. This power provides the ability to make other exemptions to the prohibition to recognise those changes and developments. Any such use of the power would first be subject to a duty to consult, so any exemption introduced by the

power will have been consulted on and will be well considered. It was not appropriate or possible to set out all exemptions on the face of the bill for the reason that the policy needs are constantly evolving as is the medium which is being regulated.

739. As noted above, the Government conducted an extensive consultation with stakeholders, which showed that there was a general desire for flexibility given the rapid developments in this industry. A delegated power enables the Secretary of State to adapt the restrictions in the light of feedback from stakeholders. This proposed power is intended to provide for legal certainty and flexibility in introducing regulations in respect of on-demand services. Delegated legislation is considered justified in this case because it will allow the government policy to evolve promptly in response to ongoing developments in scientific knowledge and food standards and changing environmental priorities and changing social and economic circumstances.

740. Section 368FA(5)(c)(i) allows the Secretary of State to quickly respond to changes in scientific and nutritional developments and amend food types and categories where appropriate following consultation with industry. The use of delegated legislation will allow the government policy to evolve promptly in response to ongoing developments in scientific knowledge and food standards and changing environmental priorities and changing social and economic circumstances.

741. Section 368FA(5)(e) confers upon the Secretary of State powers to specify a description of what can be classified as a "food or drink SME", and therefore exempt from this regulations. Providing for this in delegated legislation allows the Secretary of State to adapt to industry changes.

742. Section 368FA(6) provides a flexible power to keep in step with changes to technical guidance regarding less healthy food. Matters concerning scientific and industry based knowledge on nutritional matters are likely to require technically detailed provisions which would not be appropriate for primary legislation. The Department foresees that it may need to change guidance in response to scientific, economic and other conditions affecting specific food sectors. For example, changes in science concerning nutrition which may touch on issues such as recommended daily allowances for sugar and salt intakes. It is not possible to predict precisely what those changes should be. This power will additionally allow for consistency across Government obesity policies if the guidance were to be update. Given the pace of developments in technology and the conduct which might need to be undertaken by businesses in order to keep up with these developments, it is appropriate that the details of the technical guidance is contained in secondary legislation. A flexible delegated power is therefore sought to effect these changes in response to sector specific needs and requirements as they arise both in relation to the television programme services (as noted above) and the on-demand services.

Justification for the procedure

743. The negative procedure for regulations made under section 368FA(3) is considered to provide an appropriate level of parliamentary scrutiny because amendments are likely to

be largely technical in nature relating to the removal of categories of advertising caught by the restrictions and wide consultation with industry will inform the necessary content of regulations made under this power. Sector-specific exemptions made under this power exempting categories of advertisements from the restrictions should not give rise to any controversial issues as use of the power would be subject to a duty to consult. The power allows for further exemptions to be made to restrictions to take account of the evolving nature of the policy and future changes in food standards.

744. Provisions made under sections 368FA(5)(c)(i) and(e) for defining "less healthy" and an SME will largely be of a technical or administrative nature. The fundamental principle of the policy is provided for in the Bill with these elements being more a matter of detail and operational in nature. Therefore, the negative procedure is proposed. Given the limitations on these powers and the technical nature of the regulations there are unlikely to be policy issues that would merit time being spent by Parliament in debate.

745. Provisions made under section 368FA(6) will largely be of a technical or administrative nature. However, the affirmative procedure is sought as the Department considers it should apply where the power is exercised to modify primary legislation (as in this case). This ensures that such regulations are afforded the appropriate degree of parliamentary scrutiny when changes to primary legislation are made.

746. It would also be important for Parliament to debate the implications of any changes to technical guidance that may impact on the food in scope of the policy. The exercise of this power may have important budgetary implications on businesses caught by the restrictions. It is therefore important that the consideration of the effect on food manufacturers, broadcasters and providers of online services is fully debated, given the current significance of the guidance to the policy.

Online advertising of less healthy food and drink

***Paragraph 3 of schedule 16 inserts new section* 368Z14: Prohibition of paid-for advertising of less healthy food and drink into the Communications Act 2003**
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: section 368Z14(4), section 368Z14(6)d(i), section 368Z14 (6)(g) and section 368Z14(6)(f): negative. Section 368Z14(7): Affirmative

Context and Purpose

747. **New section 368Z14** relates to online advertising and enables the Secretary of State to make regulations in relation to the prohibition of paid for advertising of less healthy food and drink online. It contains five regulation making powers.

748. Section 368Z14(4) confers the Secretary of State with powers to exempt categories of advertisements from the restrictions. It is subject to a requirement to consult under section 368Z14(5).

749. Section 368Z14(6)(d)(i) confers upon the Secretary of State powers to specify a description of what can be classified as “less healthy” for the purpose of this section.

750. Section 368Z14(6)(f) confers a power on the Secretary of State to define “food or drink SME”.

751. Section 368Z14(6)(g) confers a power on the Secretary of State to define services connected to regulated radios services.

752. Section 368Z14(7) provides the Secretary of State with a power to amend by regulations the meaning of the relevant technical guidance regarding less healthy foods which is defined at section 368Z14(6)(e).

Justification for taking the power

753. Section 368Z14(4) provides the Secretary of State with a delegated power that enables him to respond swiftly to developments in technologies and changes in the industry to this policy as it develops. As explained above in relation to the other advertising mediums, this policy is likely to evolve with industry making changes to its products to address health concerns. This power provides the ability to make other exemptions to the prohibition to recognise those changes and developments. Any such use of the power would first be subject to a duty to consult, so any exemption introduced by the power will have been consulted on and well considered. It was not considered appropriate or helpful to set out all exemptions on the face of the Bill given the policy needs are constantly evolving as is the medium which is being regulated.

754. As mentioned in relation to the other two advertising mediums the Government conducted an extensive consultation with stakeholders, which showed that there was a general desire for flexibility given the rapid developments in this industry. These delegated powers enable the Secretary of State to adapt the various restrictions in the light of continued experience of operating them and feedback from stakeholders.

755. This proposed power is intended to provide for legal certainty and flexibility in introducing regulations. The use of delegated legislation allows the government policy to evolve promptly in response to ongoing developments in scientific knowledge and food standards and changing environmental priorities and changing social and economic circumstances.

756. Section 368Z14(6)(d)(i) provides a delegated power that enables the Secretary of State to respond swiftly to developments in technologies and changes in the industry to this policy as it develops. The policy is one that is likely to evolve with industry making changes to its products to address health concerns. This allows for flexibility in relation to “less healthy” products.

757. Section 368Z14(6)(f) relates to section 368Z14(2) which provides that food or drink SMEs are exempt from the prohibition on paying for advertisements for a less healthy food or drink product to be placed on the internet. The power under section 368Z14(6)(f) provides the definition of an SME for these purposes. This ensures that burdens are

minimised for small businesses where the impact of the policy is greater on revenue streams. This will ensure that the restrictions are proportionate. It also allows flexibility for the criteria to be adjusted with changing economic conditions. For example, the regulations might initially provide that an SME must have fewer than 250 employees, but at a later date a higher or lower number might be more appropriate.

758. Section 368Z14(6)(g) relates to section 368Z14(3)(c) which provides that services connected to regulated radio services are exempt from the prohibition on paying for advertisements for a less healthy food or drink product to be placed on the internet. This confirms that services which are connected to regulated broadcast radio and available online are exempt from the provision and not in scope. This replicates the position for broadcast radio which is out of scope of the restriction and ensures a consistent approach to adverts played on regulated broadcast radio and where those services are accessed online. The power provides the Secretary of State with flexibility in order to define those services and adapt to changing industry practices within the scope of the regulations made under this power.

759. Section 368Z14(7) provides a flexible power to keep in step with changes to technical guidance regarding less healthy food. Matters concerning scientific and industry based knowledge on nutritional matters are likely to require technically detailed provisions which would not be appropriate for primary legislation. The Department foresees that we may need to change guidance in response to scientific, economic and other conditions affecting specific food sectors. For example, changes in science concerning nutrition which may touch on issues such as recommended daily allowances for sugar and salt intakes. It is not possible to predict precisely what those changes should be. This power will additionally allow for consistency across Government obesity policies if the guidance were to be update. Given the pace of developments in technology and the conduct which might need to be undertaken by businesses in order to keep up with these developments, it is appropriate that the details of the technical guidance is contained in secondary legislation. A flexible delegated power is therefore sought to effect these changes in response to sector specific needs and requirements as they arise

Justification for the procedure

760. The negative procedure is proposed for the first four regulation-making powers. Provisions made under these powers will largely be of a technical nature relating to the removal of categories of advertising caught by the restrictions and wide consultation with industry will inform the necessary content of regulations made under this power.

761. Sector-specific exemptions made under section 368Z14(4) exempting categories of advertisements from the restrictions should not give rise to any controversial issues as use of the power would be subject to a duty to consult and the power allows for further exemptions to be made to restrictions to take account of the evolving nature of the policy and future changes in food standards.

762. Provisions made under section 368Z14(6)(g)for defining an SME and services connected to regulated radio will largely be of a technical or administrative nature.

Therefore, the negative procedure is proposed. Given the limitations on this power and the technical nature of amendments, there are unlikely to be policy issues that attract in depth Parliamentary debate and consideration. Provisions made under section 368z14(7) will largely be of a technical or administrative nature. However the Department considers that the affirmative procedure should apply where the power could be exercised to modify primary legislation (as in this case). It would also be important for Parliament to debate the implications of any changes to technical guidance that may impact on the food in scope of the policy. The exercise of this power may have important budgetary implications on businesses caught by the restrictions. It is therefore important that the consideration of the effect on food manufacturers, broadcasters and providers of online services is fully debated, given the current significance of the guidance to the policy. This is also in line with the suggested approach to the similar power in respect of television programme services and on-demand services.

Paragraph 3 of schedule 16 inserts new section 368Z18: **Guidance about functions under this part**

Power conferred on: Appropriate Regulatory Authority
Power exercised by: Guidance
Parliamentary procedure: None

Context and Purpose

763. Section 368Z18(1) requires the Appropriate Authority to draw up, review and revise guidance setting out their intentions concerning the exercise of their functions to assist with compliance with the new regulations imposed. The guidance will provide support on how the Regulator will interpret and enforce definitions. For example, what constitutes an identifiable product. It will also set out how the new prohibition will interact with the existing enforcement regime and how exemptions will be applied in practice. The guidance must, in particular, give information about the factors that the Appropriate Authority would consider it appropriate to take into account when exercising their functions under Part 4C of the Communications Act 2003.

764. Section 368Z18(3) requires that the guidance is published. Before producing such guidance, section 368Z18(2) imposes a duty on the Appropriate Authority to consult with the Secretary of State. The Appropriate Authority will have the power to amend or revise the guidance.

765. Under Section 368Z19 OFCOM may designate any body corporate to be, to the extent provided by the designation, the appropriate regulatory authority for the purposes of any provision of Part 4C of the Communications Act 2003, subject to the test set out at subsection (9). If no body is designated for a purpose, OFCOM is the Appropriate Regulatory Authority for that purpose. OFCOM may act as the appropriate regulatory authority for that purpose concurrently with or in place of any body it has designated. OFCOM must publish any designation in such manner as they consider appropriate for bringing it to the attention of persons whom, in their opinion, are likely to be affected by it.

Justification for taking the power

766. The guidance will provide further details as to the approach and enforcement of the new functions. It will contain practical and procedural details as to how those statutory requirements can and should be met. It is anticipated that this guidance may need updating more frequently than Parliament can be expected to legislate for by primary legislation. It is also anticipated that the guidance will be detailed in a way which would be inappropriate for primary legislation (but will be of assistance to the relevant regulators). It is not expected that the guidance would be considered controversial, and accordingly it is considered appropriate to use guidance for this purpose.

Justification for the procedure

767. The provision to be made is administrative rather than legislative in character. Therefore, no Parliamentary procedure is considered necessary.

Paragraph 3 of schedule 16 inserts new section 368Z20: **Power to amend this Part to extend prohibition**
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Affirmative

Context and Purpose

768. **Section 368Z20** enables the Secretary of State to make regulations to amend the inserted Part 4C of the Communications Act 2003 for the purpose of prohibiting persons from placing on the internet advertisements for an identifiable less healthy food or drink product; or making arrangements for advertisements for an identifiable less healthy food or drink product to be placed on the internet, so far as they are not already prohibited.

769. This a Henry VIII power for the Secretary of State to expand the scope of Part 4C of the Communications Act 2003 by regulations, so as to allow for further restrictions on advertising of less healthy foods and drinks to be applied at a future date. Section 368Z20(2) provides the Secretary of State with a power to amend provisions under other pieces of primary legislation (including devolved legislation) whenever made or passed in order to make any incidental, supplemental, consequential and transitional provision as the Secretary of State thinks fit (as provided for under section 402(3)(c) of the Communications Act 2003).

770. This power is also subject to a requirement to consult under section 368Z20(3).

Justification for taking the power

771. Taking a delegated power to broaden the parameters of the restrictions allows the Government to bring into scope owned media in the future as evidence emerges as to the impact of advertising of less healthy food and drink on owned sites has to children

The nature of these developments is uncertain, therefore it is necessary for the Department to have a flexible power.

772. It allows the Government to respond to changes and developments in this owned media space and set its strategic priorities for addressing the impact that advertisements of less healthy foods are having on children. It is not considered appropriate to set out such strategic priorities in primary legislation; by their nature they will change over time.

Justification for the procedure

773. The affirmative procedure is sought as it is important for Parliament to have the opportunity to debate such changes to the scope of the restrictions to ensure the implications and burdens of the extension of the restrictions on industry are fully considered. It is also a Henry VIII power and therefore the affirmative procedure is also considered appropriate.

Hospital food standards

Clause 126: Hospital food standards - power to make regulations in connection with food or drink provided or made available to any person on hospital premises in England that are used in connection with the carrying on of a regulated activity (service related to health and social care services in which registration with the CQC is required).
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative if caught by section 162 (3) of the 2008 Act. Otherwise negative.

Context and purpose

774. In response to the findings of The Independent Review of NHS Hospital Food, published on 26th October 2020[11], the Government has committed to further measures designed to prioritise the provision of healthy, nutritious food in hospitals to ensure that patients, staff and other members of the public are able to eat well in a hospital environment where patients, and in some cases staff and visitors, are reliant on the food provided or sold in hospitals. While compliance with the NHS Food Standards is written into the NHS Standard Contract, this has led to inconsistent practices across local hospital areas with some hospitals taking much greater care than others to adhere to general food standards. The Independent Review of NHS Hospital Food recommended that improved NHS food and drink standards for patients, staff and visitors be put on a statutory footing. The intention of the delegated legal power is to provide legal certainty and clarity and, in so doing, lead to greater compliance with consistent food standards across hospital trusts in England in furtherance of the best interests of the health and wellbeing of patients, visitors and staff. It will also ensure that all hospitals are on a level playing field.

775. The proposal is therefore to create a regulation making power which will provide the Secretary of State with a delegated power to set and amend regulations imposing requirements and standards in connection with the provision and sale of food or drink to patients, hospital staff, visitors or anyone else on hospital premises in England. Such requirements include the power to stipulate nutritional standards, or other nutritional requirements, such as to specify descriptions of food or drink that are not to be provided or made available. Such regulations may make provision about enforcement.

776. Section 20(3)(da) of the 2008 Act therefore affords the Secretary of State with a delegated power by regulations made by statutory instrument to impose requirements (as he/she seem appropriate) in connection with food or drink provided or made available to any person on hospital premises in England that are used in connection with the carrying on of a regulated activity (service related to health and social care services in which registration with the CQC is required). Such requirements include the power to specify nutritional standards, or other nutritional requirements, such as to specify descriptions of food or drink that are not to be provided or made available.

([11]) https://www.gov.uk/government/publications/independent-review-of-nhs-hospital-food

777. Section 20 (4B) of the 2008 Act affords the Secretary of State a power to specify that regulations made in relation to food and drink under the new subsection (3)(da) may be in relation to specific nutritional standards or other nutritional requirements. For example, to specify descriptions of food or drink that are not to be provided or made available.

778. This proposed power is intended to provide for legal certainty and flexibility in introducing regulations. Delegated legislation is justified in this case because it will allow government policy to evolve promptly in response to ongoing developments in scientific knowledge and food standards and changing environmental priorities, social and economic circumstances.

779. Regulations made under Section 20(3)(da) of the 2008 Act may also provide for the enforcement of the food standards under the existing statutory regime for example, conferring powers of entry, imposing penalties, creating offences and providing for appeals. This power will allow the current enforcement requirements to be replicated for any standards which may be introduced. This will provide consistency in the way that the standards are enforced by the CQC and is in keeping with the current standard enforcement regime across all the regulated activities enforced by the CQC.

780. The Secretary of State is required to consult representatives of the sector, or persons who may be affected, before making new specific provisions under these powers.

781. Section 162 of the 2008 Act sets out the Parliamentary scrutiny for regulations made under section 20. Any regulations made under section 20(3)(da) will be subject to affirmative requirements if they are caught by s.162(3) of the 2008 Act. In any other case, the negative procedure applies.

Justification for taking the power

782. Changes to hospital food standards to keep in harmony with scientific knowledge on nutritional matters are likely to require technically detailed provisions which would not be appropriate for primary legislation.

783. Regulations under this power will set out requirements tailored to the specific needs of hospital service users. These requirements will be based on existing specifications which are currently contained in numerous food standards across the sector which are too detailed and technical for primary legislation. The Department also foresees that we may need to change these standards in response to scientific, economic and other conditions affecting specific food sectors. For example, changes in science concerning nutrition. It is not possible to predict precisely what those changes should be, therefore a flexible delegated power is sought in the Bill to effect these changes in response to sector specific needs and requirements as they arise.

Justification for the procedure

784. The affirmative procedure will be used for any regulations which provide for offences that fall within the requirements of section 162(3)(b) of the 2008 Act, otherwise they would be subject to negative procedure (see section 162(1) and (3)(b)).

785. There is an existing duty on the Secretary of State to consult on regulations introduced under section 20(8) of the 2008 Act, which will apply to these provisions. This procedure will also guarantee scrutiny of the degree of consultation with industry, to ensure their input on the level and type of enforcement required to dissuade non-compliance.

Food information for consumers: power to amend retained EU law

Clause 127: Food information for consumers, inserting section 16(3A) and section 16(3B) into the FSA 1990 - power to amend retained EU law and make regulations concerning the provision of food information requirements tailored to suit domestic consumer needs

Power conferred on: Secretary of State / Welsh Ministers/ Scottish Ministers
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

786. Claus127 amends the FSA 1990 by introducing section 16(3A) and section 16(3B) which empower the Secretary of State and Ministers of Scotland and Wales to make regulations to amend and modify FIC. FIC has the status of retained direct principal EU legislation in accordance with section 7(6) of EUWA.

787. The clause amends the FSA 1990, to make provision permitting regulations made using the existing power under section 16(1)(e) of that Act to amend FIC. Section 16(1)(e) provides the ability to make regulations imposing requirements or prohibitions as to, or otherwise regulating, the labelling, marking, presenting or advertising of food, and the descriptions which may be applied to food.

788. The power in section 16(3A) and section 16(3B) will be used to make regulations concerning the provision of food information requirements tailored to suit domestic consumer needs. The power will allow government policy to evolve in response to changing environmental priorities and changing social and economic circumstances.

789. The power will also confer the power for provisions for Wales and Scotland, to be exercised by Ministers in those territories. It will enable the Secretary of State and Scottish and Welsh Ministers to ensure that labelling and other requirements in relation to food information are able to adapt to ongoing developments and scientific opinion.

Justification for taking the power

790. A delegated power enables the Secretary of State (where he deems appropriate) to adapt the existing regime concerning the provision of food information to consumers in response to the specific needs of domestic consumers (for example, nutritional information to support public health needs of the population) and in response to feedback from stakeholders concerning operating within the restrictions. The level of technical detail involved in amendments to the retained legislation in FIC is deemed too high for inclusion in primary legislation. For example, changes may be made to both front of pack and back of pack labelling requirements in order to deliver a particular policy

791. The content of FIC (which relates to the provision of food information to consumers and includes labelling of food) overlaps with the provision that may be made under the

existing regulation making power in section 16(1)(e) FSA 1990 and it is the Department's view that it is therefore appropriate that regulations made using that power should now have the ability to amend the provisions under FIC.

792. When the UK was a member of the EU food labelling requirements were to a large extent harmonised across the EU under FIC (as it applies in the EU) - with some specified exceptions where national measures were permitted - but that is no longer of relevance now that the UK is not a member of the EU. In the absence of those harmonising provisions, it would have been open to the UK to make regulations using section 16 (1)(e) FSA 1990 to legislate in relation to food labelling requirements. The Department therefore considers that it is appropriate that the content of FIC should be treated in a consistent manner with other areas of food labelling law where the power in section 16(1)(e) could be used to make regulations.

793. As FIC has the status of retained direct principal EU legislation in accordance with EUWA, in the absence of the power conferred by clause 127 the Secretary of State and Welsh and Scottish Ministers would not be in a position to amend FIC without primary legislation (see section 7(2) EUWA). Food safety law and the requirements around food labelling can be a fast developing area and it is the Department's view that it is desirable that requirements in relation to the labelling of food should be able to adapt appropriately to evolving scientific opinion and other developments in the area.

794. Delegation of these powers is important to ensure sufficient agility to accommodate future changes. The power would also allow future amendments to food labelling law made using section 16(1)(e). The Department foresees that we may need to change these requirements in response to scientific, economic and other conditions affecting specific food sectors. For example, changes in scientific advice concerning nutrition. It is not possible to predict precisely what those changes should be; therefore, a flexible delegated power is sought in the Bill to effect these changes in response to sector specific needs and requirements as they arise.

795. The power is a broad one but is subject to a number of safeguards; regulations are to be made via the affirmative procedure and there is a general duty to consult in matters concerning food law. Article 9 of Regulation (EU) 178/2002 (which is retained EU law) places a statutory requirement to consult on changes to food law.

796. It is worth noting that there are provisions within FIC which permit regulations to be made under the FSA 1990 by way of derogation from some of the requirements of FIC or to make clear that regulations may be made under the FSA 1990 to set out additional rules over and above those set out in FIC. These regulations are referred to as "Type A regulations" and were introduced by the Food Amendment (EU Exit) Regulations 2019 S.I. 2019/529 in order to ensure the continued operability of FIC post EU Exit, where FIC itself permitted the making of "national rules".

<u>Justification for the procedure</u>

797. It is proposed that the power will be subject to the affirmative procedure in recognition of the status of FIC as retained direct principal EU legislation.

798. This procedure will also guarantee scrutiny of the degree of consultation with industry, to ensure their input on the level and type of enforcement required to appropriately dissuade non-compliance.

799. The affirmative procedure will also ensure that adequate parliamentary scrutiny is afforded in order to achieve a suitable balance between the protection of consumers and their public health and the commercial interests of affected businesses and the objectives which these powers seek to achieve.

Fluoridation of water supplies

Clause 128(2)(d): Fluoridation of water supplies, i*nserting new subsection 87(6A) to the Water Industry Act 1991 - regulation making power enabling the Secretary of State to disapply, in the circumstances prescribed in those regulations, the provision under which water undertakers must be reimbursed for the costs of water fluoridation schemes.*
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

800. Under the current provisions of the WIA, the Secretary of State enters into arrangements with water undertakers to fluoridate the water in a specified area of England. Section 87(6) WIA requires the terms of the arrangements to include a provision that the Secretary of State reimburses the water undertaker's reasonable capital and operating costs for operating the water fluoridation scheme in question.

801. The purpose of the regulation making power in the new section 87(6A) of the WIA (as inserted by clause 128(2)(d)) is to enable the Secretary of State to disapply the requirement that any arrangements with the water undertaker must include a reimbursement clause for capital and operating costs. The practical effect of this delegated power is to enable the Secretary of State to share the costs of water fluoridation with water undertakers in the circumstances prescribed.

Justification for taking the power

802. The power will enable the costs of water fluoridation to be shared beyond central government, should such a decision be taken in the future. The wider amendments to the WIA are intended to make it easier to increase the number of water fluoridation schemes operating in England.

803. The transfer of power in the Bill from local authorities to Secretary of State will also transfer responsibility for operational costs, which currently are the responsibility of local authorities. Central Government are already responsible for capital costs. Any future proposals to expand water fluoridation will require funding to be secured. The Department wishes to include this power in the Bill in order to enable some form of cost sharing to take place with water companies, should such decisions been made in the future. The regulations will also allow the necessary flexibility to specify the circumstances in which water companies are not reimbursed for costs associated with water fluoridation.

804. Before making regulations under the power in new section 87(6A) of the WIA, the Secretary of State is required to consult such persons as the Secretary of State considers appropriate. Clause 128(2)(f) inserts new section 87(7G) to this effect.

Justification for the procedure

805. The procedure proposed for this delegated power is the affirmative procedure. Although not strictly a Henry VIII power, as the current section 87(6) will be subject to the regulation making power in section 87(6A), the Department considers the affirmative procedure appropriate to ensure proper parliamentary scrutiny of any regulations made under that provision.

Clause 128 : Fluoridation of water supplies, *inserting new subsection 87(6B) into the Water Industry Act 1991 - regulation making power to enable the Secretary of State to require the costs of water fluoridation schemes to be shared beyond central Government.*
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

806. Under the current provisions of the WIA, the Secretary of State enters into arrangements with water undertakers to fluoridate the water in a particular area of England. Section 87(6) requires the terms of the arrangements to include a provision that the Secretary of State reimburses the water undertaker's reasonable capital and operating costs for operating the water fluoridation scheme in question.

807. Section 88H enables the Secretary of State to pass on any of these costs to local authorities since they are currently responsible for initiating water fluoridation schemes. At present, the Secretary of State requires the local authorities to pay for the operational costs of the water fluoridation schemes, whilst central Government bears the capital costs.

808. Section 88H is repealed as part of the amendments to the WIA (by virtue of clause 128. The new delegated power in section 87(6B) (as inserted by clause 128 is intended to replace section 88H, though enabling the cost-sharing to apply more broadly, to such public bodies as may be specified.

Justification for taking the power

809. The power will enable the costs of water fluoridation to be shared beyond central Government. There are existing powers to share costs with local authorities under section 88H. Following the successful passage of the Bill, operational costs, currently met by local authorities will also transfer to the Secretary of State, alongside the powers to directly introduce, vary or terminate schemes. Water fluoridation is a clinically effective measure to improve oral health and reduce oral health inequalities. The Secretary of State therefore wishes to have the flexibility to enter into cost sharing arrangements with public sector bodies such as the NHS or local authorities, that may benefit from such improvement (for example, in terms of savings associated with the numbers of children currently having tooth extractions under general anaesthetic due to

entirely preventable tooth decay.) The delegated power is limited to public bodies, so the Secretary of State would not be able to require individuals or businesses (other than water undertakers)[12] to cost share fluoridation costs.

810. The regulations will allow the necessary flexibility for the Secretary of state to specify precisely which costs are to be shared, and to what extent they are to be shared between the public body and the Secretary of State.

811. Before making regulations under the power in new section 87(6B) of the WIA, the Secretary of State is required to consult such persons as the Secretary of State considers appropriate. Clause 128) inserts new section 87(7G) to this effect.

Justification for the procedure

812. The power is subject to the negative procedure as there is a statutory requirement to consult prior to making the regulations.

Clause 128 : Fluoridation of water supplies - ***this clause applies section 89 of the WIA to England (as well as Wales, as at present) and in doing so, confers powers on the Secretary of State to make regulations in relation to the consultation required by that section.***
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

813. Under the current provisions of the WIA, local authorities are required to consult and ascertain opinion before requesting the Secretary of State to enter into an arrangement with the water undertaker for a new fluoridation scheme to vary or terminate an existing scheme in England. There are powers in section 88E WIA for the Secretary of State to make regulations prescribing the factors which must be taken into account when deciding whether to proceed with a fluoridation proposal. In section 88O(1) WIA, there is an additional regulation making power in relation to the circumstances in which consultation is required for any decisions on maintenance of fluoridation schemes[13].

814. Sections 88E and 88O of the WIA are repealed by clause 128 as part of the wider amendments to the WIA intended to enable the increase in the number of water fluoridation schemes operating in England by transferring the power to initiate such schemes to the Secretary of State. Clause 128, however, also amends section 89 of the WIA (consultation) so that it applies in relation to England (as well as Wales, as at present). The effect of the amendments is to require the Secretary of State to i) consult

[12] See the delegated power in section 87(6A) which enables the Secretary of State to cost share with water undertakers.

[13] The Water Fluoridation (Proposals and Consultation) (England) Regulations 2013 are the regulations made pursuant to these delegated powers.

and ascertain opinion in accordance with regulations and ii) comply with the procedure set out in regulations, before initiating, amending, varying or terminating any water fluoridation schemes; and also to confer regulation making powers on the Secretary of State in relation to i) and ii).

Justification for taking the power

815. The amendments to section 89 of the WIA (consultation), which place a duty on the Secretary of State to consult in accordance with regulations before initiating, amending, varying or terminating a fluoridation scheme, necessitate the conferral of the power on the Secretary of State to make such regulations. Section 89(3) provides more detail as to what these powers entail, relevantly that the regulations shall include a) provision for the process the Secretary of State must follow when consulting and b) provision about the requirements which must be satisfied (with respect to the outcome of that process or otherwise). These powers will ensure there is certainty around the content and form of each water fluoridation consultation and the procedure to be followed, whilst still providing flexibility to the Secretary of State in determining how the process is undertaken in practice.

Justification for the procedure

816. This power enables the details of the consultation to be set out in regulations, and as such the power is subject to the negative procedure. Further, it is in effect an existing power (subject to the negative procedure), being applied to the Secretary of State together with the remainder of section 89 of the WIA.

PART 6

General powers

Clause 130 : Power to make consequential provision
Power conferred on: Secretary of State
Power exercised by: regulations
Parliamentary Procedure: negative procedure, unless amending or repealing provision made by primary legislation, in which case affirmative

Context and purpose

817. This clause contains a power to make provision that is consequential upon this Bill.

Justification for taking the power

818. This Bill includes a significant number of amendments which relate to a very complex and interlinking legislation framework for the NHS. This is particularly so in respect of the 2006 Act and the 2012 Act and so it is considered necessary to include a consequential power which would allow us to amend any Bill provisions which are being inserted into that framework.

819. The powers conferred by this clause are wide, but there are various precedents for such provisions including section 92 of the Immigration Act 2016, section 213 of the Housing and Planning Act 2016, section 115 of the Protection of Freedoms Act 2012, section 59 of the Crime and Courts Act 2013 and 41 section 73(2) of the 2014 Act.

Justification for the procedure

820. This power enables the Secretary of State to make consequential amendments to primary and secondary legislation by secondary legislation. In respect of primary legislation, it is therefore a Henry VIII power. In line with the usual practice, regulations made under this power which amend primary legislation will be subject to the affirmative procedure. Regulations which do not amend primary legislation will be subject to the negative procedure. This is considered proportionate in light of the fact that regulations made under this power may only be made if they are genuinely consequential upon provisions of the Bill.

Clause 134 : Commencement
Power conferred on: Secretary of state
Power exercised by: regulations made by statutory instrument
Parliamentary Procedure: no procedure

Context and purpose

821. This clause contains a standard power for the Secretary of State to bring provisions of the Bill into force by commencement regulations.

822. It also contains a standard power for a Minister of the Crown to make transitional, transitory or saving provision in connection with the bringing into force of provisions of the Bill.

Justification for taking the power

823. As is usual, it may be sensible for parts of the Bill to commence at different times, where the commencement is not already stated. This power enables that.

Justification for the procedure

824. As is usual with commencement powers, regulations made under this clause are not subject to any parliamentary procedure. Parliament has approved the principle of the provisions to be commenced by enacting them; commencement by regulations enables the provisions to be brought into force at the appropriate time.

Department of Health and Social Care

6th July 2021